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(בעברית) (Hebrew)
שיטות והתקנים לניתוחים בכלי דם

(באנגלית) (English)
METHODS AND DEVICES FOR VASCULAR SURGERY

מבקש בזאת כי ינתן לי עליה פטנט
hereby apply for a patent to be granted to me in respect thereof.

• בקשת חלוקה – Application of Division	• בקשת פטנט מוסף – Application for Patent Addition	• דרישה דין קדימה Priority Claim		
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METHODS AND DEVICES FOR VASCULAR SURGERY

FIELD OF THE INVENTION

The present invention relates to performing blood vessel anastomosis and especially to anastomosis relating to precutaneous bypass surgery.

BACKGROUND OF THE INVENTION

Connecting two blood vessels, anastomosis, is an important surgical technique for reconstructive, therapeutic and cosmetic surgery. The gold standard of anastomosis is manual suturing of the two blood vessels in a side to side, end to end or end-to-side configuration. Although it is generally desirable to shorten the length of any surgical procedure, this is especially important in coronary bypass surgery, in which a patient is usually attached to a heart-lung machine and his heart is often stopped.

In addition to manual suturing of blood vessels, other methods of attaching two blood vessels are known, including, staples and anastomosis rings. PCT publications WO 97/40754 and WO 97/28749, the disclosures of which are incorporated herein by reference, describe staplers for coronary bypass surgery, wherein a graft is connected on one of its ends to the aorta and at its other end to an occluded coronary artery, distal to the occlusion. In this type of surgery, the anastomosis is sealed by stapling the graft to the aorta, while pressing both aorta and graft against an anvil. In one publication, the anvil is inserted into the aorta for the stapling and then removed, possibly by taking the anvil apart. In the other publication, the end of the graft is everted over a ring-shaped anvil, so that the anvil is outside of the blood vessel at all times.

Recently, bypass surgery has been performed using minimally invasive (key-hole) surgery. In this type of surgery, a small hole is made in the chest, instead of cracking open the ribs, and the mammary arteries are used for bypass grafts. The suturing and/or stapling is performed using tools, for example as described above.

An even less invasive type of surgery requires no opening of the chest at all, rather, one or more catheters are introduced into the blood vessels using a precutaneous approach. PCT publications WO 97/27898, WO 97/13471 and WO 97/13463 and their priority documents, namely U.S. applications, 60/010,614, 60/005,164, 08/730,327 and 08/730,496, the disclosures of which are incorporated herein by reference and termed the "Transvascular Applications", describe method and apparatus for precutaneous treatment of arterial occlusions. Two main methods are taught in these applications. In one method, a tunnel is excavated within tissue (outside the vessel) from one side of the occlusion to the other side of the occlusion, and a stent or a stent/graft may be placed within. In another method, a conveniently located vein or

graft is attached to the occluded vessel and two side-to-side anastomosis are created between the occluded vessel and the vein or graft. The distal and proximal portions of the vein are closed in one of a variety of manners. The connection between the vein and the artery may be by welding the two blood vessels, or one of a variety of connectors that are suggested. One of the disclosed connectors comprises two springs separated by a short segment of a possibly unstented graft. The springs have the form of an inverted funnel, so that the two blood vessels are urged together. Where there is a spacing between the blood vessels, various techniques and/or devices are suggested for stopping the surrounding tissue from compressing the connection between the vein and the artery. One of the purposes of the various types of connectors is to maintain the two blood vessels near each-other, either in contact or compressing tissue between them, presumably so no blood will leak from the connection between the connector and the blood vessels.

In a TIPS procedure, a stent is placed into a passage precutaneously forced, opened or excavated between a portal vein and a hepatic vein. As in some of the embodiments described in the previous paragraph, the relative location of the blood vessels is maintained by the existence of relatively solid tissue surrounding and between the two blood vessels. Thus, there is no requirement that each of the connections between an end of the connector and the respective blood vessel to which it is attached, be, of itself, leak-proof.

In WWW publication "http://me210abc.stanford.edu/94-95/projects/Pfizer/Spring/1.html", the disclosure of which is incorporated herein by reference, a method is described for reducing the complexity of performing a bypass surgery. In this method, a graft is precutaneously brought to the aorta and pushed out of an incision in the aorta near a site of a bypass surgery. A keyhole opening is made in the chest to bring a tool to suture or staple the graft to the aorta and to the coronary which is to be bypassed.

SUMMARY OF THE INVENTION

One object of some preferred embodiments of the invention is to provide a minimally invasive method of bypassing occluded blood vessels, without sacrificing a nearby artery or vein.

Another object of some preferred embodiments of the invention is to provide improved anastomosis connectors, especially suitable for minimally invasive surgery.

One aspect of some preferred embodiments of the invention relate to bringing, through the vasculature, a blood vessel graft to a location on a blood vessel and performing an independent and patent anastomosis between the graft and the blood vessel. By independent it is meant that the anastomosis does not leak, regardless of whether or not the other end is

connected. In a preferred embodiment of the invention, the anastomosis is an end-to-side anastomosis, preferably the end being an end of the graft. Alternatively, the anastomosis is an end-to-end, side to side or diagonal anastomosis. In a preferred embodiment of the invention, the blood vessel is an Aorta.

In a preferred embodiment of the invention, the other end of the graft is also attached, via at least one additional anastomosis to a blood vessel other than the first blood vessel. The anastomosis is preferably of an end to side type, with the end preferably being an end of the graft. Alternatively or additionally, the graft is connected to a plurality of blood vessels, preferably using a plurality of side-to side anastomoses along its length. Alternatively or additionally, the graft is forked or otherwise has more than two ends each of which is preferably attached to different blood vessels or different positions on the same blood vessel.

In a preferred embodiment of the invention, these other anastomoses are also performed precutaneously. Alternatively or additionally, these anastomoses are made using key-hole surgery.

In one preferred embodiment of the invention, the graft is a patch to be applied to the outside and/or inside of the blood vessel, rather than being a blood carrying vessel of itself. Thus, only one end of the graft is ever connected to a blood vessel.

Another aspect of some preferred embodiments of the present invention relate to precutaneously performing an end-to-side anastomosis. In a preferred embodiment of the invention, no tissue is cut out of the "side" vessel of the anastomosis. Rather, a hole is made in the "side," and which is enlarged to match the diameter of the "end". Alternatively or additionally, the anastomosis is made between a blood vessel and a graft. Preferably, the graft is brought through the "side" blood vessel and pushed out through the hole. Preferably, the anastomosis is performed transvascularly. Preferably, the anastomosis is made from within the blood vessel.

Another aspect of some preferred embodiments of the invention relates to creating a bypass blood flow channel between an aorta and one or more coronary blood vessels, without creating holes in the body, except for vascular ports.

Another aspect of some preferred embodiments of the invention relates to precutaneously creating a long flexible graft connection between two blood vessels. Preferably, the graft is brought to the site of the connection through the vasculature. Preferably, the graft is longer than twice its diameter. Alternatively or additionally, the graft is longer than five times its diameter. Alternatively or additionally, the graft is longer than 10 times its diameter. Alternatively or additionally, the graft is longer than 20 times its diameter.

Alternatively or additionally, the graft is longer than 50 times its diameter. In a preferred embodiment of the invention, the graft is longer than 1 cm. Alternatively or additionally, the graft is longer than 2 cm. Alternatively or additionally, the graft is longer than 5 cm. In a preferred embodiment of the invention, the two points on the blood vessels which are bridged by the graft are at least 2 cm, 5 cm, 7cm or 15cm apart. Alternatively or additionally, the points are at least 3, 6, 10, 15, 20 or 50 graft diameters apart. In a preferred embodiment of the invention, the straight line distance between the two points is less than 70%, 60%, 50% or even less than 40% of the length of the graft.

In a preferred embodiment of the invention, the graft lies along a substantially straight line. Alternatively or additionally, the graft lies along a line having a bend of over 50, 60, 70, 90, 120 or even 140 degrees. In a preferred embodiment of the invention, an angle between the axis of the graft at one end thereof and the axis of the graft at a second end thereof is over 10, 20, 30, 50, 90, 120 or 130 degrees. In a preferred embodiment of the invention, each of the anastomosis connectors defines a plane. Preferably, the angle between the planes, as measured between perpendiculars to the plains pointed in the direction of the graft is over 10, 20, 40, 60, 90, 120 or 150 degrees. In the above ranges, in certain preferred embodiments of the invention, the value of the parameter is between two range-end values, rather than being defined as open-ended.

Another aspect of some preferred embodiments of the present invention relates to navigating one end of a graft, which is attached at its other end to one blood vessel, until the first end is adjacent to a second blood vessel. Preferably, this navigation is facilitated by an ultrasound imager and/or Doppler sensor, coupled to a guide wire or a catheter on which the graft is carried. Preferably, the sensor is situated outside of the graft, so that it can better sense its surroundings.

Another aspect of some preferred embodiments of the invention relates to the anastomosis of the graft to a blood vessel, after such navigation. In a preferred embodiment of the invention, the anastomosis is a side to side anastomosis. Alternatively or additionally, the anastomosis is an end-to-side anastomosis. Preferably, the anastomosis is started using a barbed guide-wire or a screw-tipped guide wire which captures the target blood vessel. The graft is then preferably pulled along the guide wire to the target blood vessel and attached thereto. Preferably, the attachment is by pushing the end of the graft, preferably with an anastomosis connector attached thereto, into a small hole in the target blood vessel and increasing the diameter of the anastomosis.

Another aspect of some preferred embodiments of the invention relates to performing an anastomosis from inside a blood vessel taking part in the anastomosis, while creating a minimal amount of contact between an anastomosis connector used for the anastomosis and the blood stream, after the anastomosis is complete. In a preferred embodiment of the invention, the anastomosis is an end-to-end anastomosis. Alternatively or additionally, the anastomosis is a side-to-side anastomosis. Alternatively or additionally, the anastomosis is an end-to-side-anastomosis.

Another aspect of some preferred embodiments of the invention relates to a graft having attached thereto one or more independent anastomosis connectors. Preferably, at least one of the connectors is attached at an end of the graft. Alternatively or additionally, at least one of the connectors is a side-to-side or side-to-end connector where the graft is the "side" element in the anastomosis.

In a preferred embodiment of the invention, at least one of the anastomosis connectors has a shape which can be changed. This can make it easier to guide such a graft through a catheter and/or endoscope lumen. In a preferred embodiment of the invention, the graft is guided through a blood vessel without an enclosing catheter. Preferably, the graft maintains a radially compressed configuration due to the radial compression of the anastomotic connectors. Alternatively or additionally, the connector are maintained radially compressed by an internal guide wire which restrains them from inflating. Alternatively or additionally, the connectors are plastically deformable. Preferably, the shape changing comprises radial shape changing, preferably expansion. Alternatively or additionally, especially where the connector is connected to the graft at a "side" side thereof, the connector is preferably distorted in a radial direction, so that in its distorted shape at least one radii thereof fits in a desired lumen diameter.

In a preferred embodiment of the invention, at least one anastomosis connector comprises an everting connector, such that at least one side of the anastomosis, e.g., the graft, is everted over the connector.

In a preferred embodiment of the invention the graft is a blood vessel from the patient, Alternatively or additionally, the graft is a xenograft. Alternatively or additionally, the graft comprises a synthetic material.

Alternatively or additionally, the graft is stented, on its inside and/or on its outside and/or in its body. Preferably, the stenting is along its entire length. Alternatively or additionally, only portions of the graft are stented, such as its ends or its middle. In a preferred embodiment of the invention, the stenting provides radial stiffness. Alternatively or

additionally, the stenting provides axial stiffness. In a preferred embodiment of the invention, the type and/or degree of stiffness provided varies along the graft. In a preferred embodiment of the invention, the stiffness is symmetrical around the axis of the graft. Alternatively or additionally, the stiffness is asymmetrical, for example, if one side of the graft is to be in contact with the heart, that side may be made stiffer.

Many types of grafts and/or stented grafts are known in the art and they are generally all suitable for use in various embodiments of the present invention.

Another aspect of some preferred embodiments of the invention relates to a method of attaching the anastomosis connector to the graft, prior to inserting the graft into the body. In a preferred embodiment of the invention, the anastomosis connector is covered with a flap of graft material and the covered connector is attached to the graft, such that the anastomosis is made via the flap. Preferably, the graft flap is glued to the graft. Alternatively or additionally, the anastomosis connector and/or the graft flap are sutured to the graft or otherwise connected, for example using short spikes. It should be appreciated that the graft flap may comprise a different material from the graft. For example, the flap may be Dacron and the graft may be a human blood vessel. In a preferred embodiment of the invention, the anastomosis connector is provided pre-attached to the flap, which is attached to the graft prior to insertion. Alternatively, the flap is attached to the connector at substantially the same time that the graft is inserted into the body. In a preferred embodiment of the invention, an end of the graft is cut off and used as a flap for the anastomosis connector.

Another aspect of some preferred embodiments of the invention relates to methods and apparatus for delivering the graft and/or the anastomosis connectors to the anastomosis site. In a preferred embodiment of the invention, the graft is pushed out through one blood vessel and is attached to he blood vessel at one end of the graft. The other end of the graft is attached to a second blood vessel or at a different location along the first blood vessel.

Some features of preferred embodiments of the present invention relate to the first anastomosis connection, while other features relate to the second anastomosis connection. With regard to the first anastomosis connection, a guide wire is preferably pushed out of an opening made in the first blood vessel and the graft is preferably brought out of the blood vessel along the guide wire. A balloon is preferably brought along the guide wire into the anastomosis connector and expanded. In some preferred embodiments of the invention, the anastomosis connector is topologically external to the blood vessel, however, due to folding of the vessels, it occupies space inside one or both the blood vessels and the graft. Preferably the anastomosis connector exits the first blood vessel when the anastomosis is completed so that it

mostly external to the graft and the blood vessel. In some cases, the connector may have to be pushed out of the blood vessel.

With regard to the second anastomosis connection, a guide wire, possible the same guide wire as for the first connection, is inserted into the second blood vessel, to create a hole in the vessel. The insertion may be done by simply pushing the guide wire into the vessel. Preferably, the guide wire is inserted into the second vessel for a considerable length. Optionally, the guide wire is bent and/or barbed so that it will not retract from the second vessel. Alternatively, a screw-tip guide wire may be used to screw the guide wire tip into the second blood vessel. The graft and the second anastomosis connection are brought along the guide wire and inserted into the hole in the second blood vessel. A balloon is preferably brought along the guide wire to inflate the anastomosis connector and widen the opening of the anastomosis between the graft and the second blood vessel.

Alternatively to using a balloon, an anastomosis connector may comprise a super elastic material. In this case, the anastomosis connector is preferably maintained in a compressed position by an enclosing element. Once the connector is in place, the enclosing element is removed and the connector expands to a desired shape. The term super elastic is used herein to denote a material which returns to a desired shape when a constraint is relived. In some cases, an elastic material may suffice. Alternatively or additionally, a shape memory alloy may be used and activated to return to the learned shape.

In a preferred embodiment of the invention, the guide wire is inserted into or out of the blood vessel at a 90 degree angle to the blood vessel. Alternatively or additionally, at least one of the insertions is performed at an oblique angle to the vessel wall, for example, less than 80, less than 60, less than 40 or less than 20 degrees. Alternatively or additionally, the final angle of the graft to the vessel is also oblique, for example, at these angles.

In a preferred embodiment of the invention, the delivery system includes a clamp and/or a suction tip for maintaining the wall of a blood vessel in a desired position while pushing a sharp guide wire tip through it.

Alternatively or additionally to using a guide wire to make a pinhole and expanding the hole using an expandable anastomosis connector, a hole puncher may be provided along the guide wire to cut out a portion of one or both the blood vessels. Alternatively or additionally, a slit or an x-shaped cut in the vessel wall may be made by the guide-wire.

Another aspect of some preferred embodiments of the invention relates to an anastomosis connector in which radial expansion/shrinkage is combined with axial expansion/shrinkage. In accordance with one preferred embodiment of the invention, when the

connector is radially expanded, it simultaneously shrinks axially. In one preferred embodiment of the invention, the connector comprises a cylinder with long spikes at each end. When the connector is first inserted, the spikes are bent to engage the blood vessels. When the cylinder is expended, the two blood vessels are forcefully brought into contact, so that a better anastomosis may result. In a preferred embodiment of the invention, the cylinder comprises an array of parallelograms. Alternatively or additionally, the cylinder comprises a solid surface with slits cut therethrough, perpendicular and/or parallel to the axis of the cylinder. In a preferred embodiment of the invention, the coupling between the two axes is meditated by the shape and other parameters of the parallelograms.

In a preferred embodiment of the invention, the coupling between the two axes is dependent on the radius. In one example, when the device is in a radially shrunk configuration, a small radial expansion will produce a large axial shrink, while when the device is in a radially expanded configuration, a small additional expansion will only cause a small additional axial shrinkage. Alternatively, other relationships between shrinkage/expansion of the two axes may be used. The type of relationship may be modifies by changing the shape and/or aspect ratio of some or all of the parallelograms. In a preferred embodiment of the invention, the relationship and/or elastic properties and/or other properties of the connector are selected for a particular vessel size being connected.

In a preferred embodiment of the invention, an anastomosis that is suspected of leaking may be repaired by radially expanding the connection by a small amount, thereby causing axial shrinkage and a stronger contact between the two blood vessels. Alternatively, a T-shaped stent may be attached over the anastomosis connector to repair the leak.

Alternatively, in some preferred embodiments of the invention, the radial expansion may be decoupled from the axial shrinkage, at least for some ranges of radial expansion.

In a preferred embodiment of the invention, the anastomosis connector comprises an elastic material. Alternatively or additionally, the connector comprises a plastic material. In one example, in which spikes are plastically bend to engage the blood vessels, the cylinder comprises a super elastic material having an expanded resting position.

In a preferred embodiment of the invention, the connector comprises steel and/or other non-absorbable materials. Alternatively or additionally, the connector comprises bio-absorbable materials, so that after a period of time, no foreign materials will remain in the body. In one preferred embodiment of the invention, at least the spikes and/or other portions of the connector which are in contact with the blood are formed of a bio-absorbable material.

In a preferred embodiment of the invention, a similar connector configuration having a coupling between radial expansion and axial contraction is used to attach two blood vessels with end-to-end or end-to-side anastomoses. Alternatively or additionally, a device with a similar configuration may be used to insert a valve in a blood vessel, such as the aorta or a vein. When the device is inflated, the spikes dig into the blood vessel to hold the valve in place. In this types of connection, axial compression is preferably minimal or non-existent. The device itself may be inserted over an existing valve, whereby the spikes and/or the cylindrical body may be used to compress the old valve against the walls of the blood vessel. Alternatively, the old valve may be cut out, in part or in full using a suitable catheter. Preferably, the valve is inserted while the heart is pumping. The valve is preferably a soft leaflet valve.

In a preferred embodiment of the invention, the anastomosis connector is used for externally performed anastomoses, instead of for an anastomosis performed from inside the blood vessel. In a preferred embodiment of the invention, two blood vessel ends are inserted into or over an anastomosis device while the device is in a compressed condition. The device is then inflated. Preferably the device comprises an elastic material so that it may be expanded by releasing a constraining ring or holder.

Another aspect of some preferred embodiments of the invention relates to simultaneously attaching two blood vessels and increasing the size of a passageway between them. Preferably, such expansion is made possible using an inflatable balloon. Alternatively, a different type of expanding framework may be used, for example, a super-elastic framework which expands when a constraint is removed or a hinged construction where pulling a wire causes the construction to increase at least one dimension thereof.

Another aspect of some preferred embodiments of the invention relates to an anastomosis connector which does not pass through both blood vessels being attached. Rather, the connector preferably follows the anastomosis joint connection between the blood vessel and the graft. Preferably, the connector includes spikes to attach ends of the connector to the blood vessels. In a preferred embodiment of the invention, when the connector is in its final position, the shape of the connector keeps the anastomosis patent by forcing the two blood vessels together, rather than by attaching them together.

Another aspect of some preferred embodiment of the invention relates to an anastomosis connector comprising one or two parts in which portions of the connector are attached to each other and in which there is a reduced requirement to align the portions, at least with respect to their rotation around the graft axis. In a preferred embodiment of the invention,

the anastomosis connector comprises two rings, one including connection spikes and the other comprising a friction material. When the anastomosis is performed, the spikes are imbedded into the friction material. Preferably, each one of the spikes passes through one or both of the blood vessels. Preferably, one or both of the rings may include eversion spikes, on which to evert the blood vessel. Alternatively or additionally, the connection spikes are used for eversion.

Alternatively or additionally, the two rings both include spikes and friction material. Alternatively or additionally, the two rings comprise a rigid material, such that some of the spikes in one ring match pre-defined holes in the other ring. In a preferred embodiment of the invention, the anastomosis connector is similar to a Nakayama ring anastomosis device, except that the rings are expandable in the present device. Preferably, the rings are expanded prior to their being connected to each other. Alternatively or additionally, the rings are expanded while being connected to each other. Preferably, the rings include a protrusion and/or a depression so that they can both be aligned, for example, using the guide wire or using a balloon with a guiding groove. Alternatively or additionally, the rings have an otherwise non-circular cross-section.

Another aspect of some preferred embodiments of the invention relate to a kit, including measuring devices for determining the diameter of a graft, a set of anastomosis connectors having different properties and a delivery system for attaching the graft. Preferably, the kit includes a device for everting the graft over an anastomosis connector.

Another aspect of some preferred embodiments of the invention relate to anastomosis where at least part of the structural support of the anastomosis connection, for example a ring, does not remain in the body. In a preferred ,embodiment of the invention, the anastomosis connector and/or the delivery system includes a collapsible framework which assures that the two blood vessels are properly aligned. However, once the two blood vessels are connected together, for example, by gluing, stapling and/or welding, the framework is collapsed and removed from the body.

In a preferred embodiment of the invention, the framework comprises an inflatable anvil against which staples are driven through both the blood vessels. Alternatively or additionally, the framework maintains the eversion of the graft and/or the blood vessel, until the anastomosis is performed.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be more clearly understood by reference to the following description of preferred embodiments thereof in conjunction with the figures, wherein identical

structures, elements or parts which appear in more than one figure are labeled with the same numeral in all the figures in which they appear, in which:

Fig. 1 illustrates a heart with at least one clogged artery and showing a desirable bypass path;

Figs. 2A-2I illustrate a bypass technique in accordance with a preferred embodiment of the invention;

Figs. 3A-3O illustrate different types of side to end and end-to end joints, achievable in accordance with preferred embodiments of the invention;

Figs. 4A-4D illustrate a one piece anastomosis connector, in a plan view and in various stages of deployment, in accordance with preferred embodiments of the invention;

Fig. 5 is a graph illustrating various possible couplings between radial expansion and axial contraction in an anastomosis connector as shown in Fig. 4A;

Figs. 6A-6E illustrate an additional one piece anastomosis connector and its deployment, in accordance with a preferred embodiment of the invention;

Figs. 7A and 7B illustrate a pin based anastomosis device, in accordance with a preferred embodiment of the invention;

Figs. 8A-8E illustrate an orientation independent two piece anastomosis device, in accordance with a preferred embodiment of the invention;

Figs. 9A-D illustrate additional devices for attaching graft material to blood vessels, , in accordance with preferred embodiments of the invention;

Figs. 10A-10D illustrate an end-to end anastomosis in accordance with a preferred embodiment of the invention; and

Fig. 11 illustrates a graft delivery system, in accordance with a preferred embodiment of the invention.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

Fig. 1 illustrates a heart 20 having an artery 22 that is clogged, for example, at an occlusion location 24. One medical solution is to provide a graft 26 which connects between an aorta 30 and a point 28 downstream from occlusion 24. Graft 26 is usually connected to aorta 30 using a side-to-end anastomosis 32. The anastomosis at point 28 is usually also a side-to-end anastomosis. However, this type of procedure generally requires at least key-hole surgery, and often open-chest surgery.

Figs. 2A-2I illustrate a bypass technique in accordance with a preferred embodiment of the invention, in which most or all of a cardiac bypass procedure may be performed

precutaneously, without opening the chest. In a preferred embodiment of the invention, a CABG (Coronary Artery Bypass Graft) procedure is performed.

Preferably, the initial step is to harvest a graft from the body of the patient or otherwise provide it. Thereafter, one or more anastomosis connectors are preferably attached to the graft. Alternatively or additionally, the graft comes with ready made anastomosis connectors attached thereto. The anastomosis connectors are preferably selected to match the blood vessel diameters, conditions and/or other parameters of the anastomosis.

Fig 2A illustrates a first step, in which a catheter 34, preferably a J-shaped catheter, is brought into contact with the wall of aorta 30, with the end of the catheter generally directed towards coronary artery 22. The catheter is preferably inserted into the body through the arterial system, for example via the femoral artery.

In Fig 2B, a thin guide-wire 36, having a sharp tip 37 is pushed out of aorta 30, creating a hole 35. Preferably, catheter 34 is pressed against the wall of aorta 30, so no blood escapes. Alternatively or additionally, and especially if the diameter of wire 36 is small, the elasticity of aorta 30 closes onto the wire and maintains leakage integrity.

In Fig. 2C a graft 38 is pushed out of hole 35 and into the chest cavity. Preferably, graft 38 is preloaded with at least one anastomosis connector, for example an aortic anastomosis connector 42 and/or a coronary anastomosis connector 40. Alternatively, one or both the connectors may be attached to the graft after it is inserted into the body.

In Fig. 2D, graft 38 is attached to aorta 30, preferably using anastomosis connector 42. Alternatively or additionally, the graft is attached by gluing, welding or suturing. In a preferred embodiment of the invention, stapling is performed via a keyhole opened in the chest. Alternatively or additionally, welding is achieved by passing an electric current through the anastomosis connector itself. Alternatively or additionally, the anastomosis is performed by expanding a balloon or another types of expandable device inside anastomosis connector 42 and the expansion causing the connector to perform the anastomosis. Alternatively or additionally, connector 42 is super elastic and once a restraint is removed, snaps into a configuration suitable for anastomosis. Alternatively or additionally, one or more balloons and/or expandable frameworks are urged against each other with connector 42 held between them, so that connector 42 creates the anastomosis.

It should be noted, that in accordance with some preferred ,embodiments of the invention, the graft-aorta anastomosis is patent on its own. Preferably, graft 38 is blocked, for example using a balloon along guide wire 36 so that blood does not leak out its distal end.

In Fig. 2E, graft 38 and/or guide-wire 36 are navigated so that tip 37 of the guide wire is near coronary artery 22. Such navigation includes two elements, first, actually guiding the guide wire and second, directing the guide wire to a correct location. In some cases, for example if the guide wire is rigid, the navigation step might be performed before the aortic anastomosis step, so that most or all of graft 38 may be removed from the aorta and the aortic connection may then be performed between the graft and the aorta.

Guiding the guide-wire may be preferred using many methods known in the art, including controllable guide wires and outer sleeves of different shapes. Direction of the guide wire may be based on a real-time image or it may be based on a pre-determined representation of the body. In a preferred embodiment of the invention, a real-time catheter location system, is used to determine the relative locations of tip 37 and point 28 on coronary 22. One such location system is available from Johnson & Johnson Biosense Ltd., of Tirat Hacarmel, Israel. Alternatively or additionally, the navigation is performed using a real-time or near real-time image provided by an imaging system, such as ultrasound, CT, fluoroscopy and MRI. In some navigation systems it may be necessary to mark point 28 (Fig. 1) or coronary 22. Such marking may be achieved by using a contrast material or a radio-opaque marker. In some cases, it may be desirable to insert a catheter into artery 22, with such a marker at its tip to facilitate navigation of catheter tip 37.

If graft 38 is already attached to aorta 30, the graft is preferably uncovered while it snakes around the inside of the body. Alternatively or additionally, an outer sleeve may cover the graft and protect it from contact with internal body tissues. If the aortic anastomosis is already performed, such a covered is preferably flexible and is preferably removed by pulling it through the "coronary" end of the graft.

An ultrasound imager, especially at or near tip 37 may also be used to determine which obstacles lie ahead of tip 37 and/or to help guide and/or position it. In a preferred embodiment of the invention, graft 38 is attached to body tissue, for example membranes, muscle, and/or blood vessels, along its length. Such attaching may be performed after the anastomosis is finished. Alternatively or additionally, such attaching is performed during the navigation step. The attaching may be achieved by pushing clips out of the lumen of graft 38 and into the tissue. Alternatively or additionally, graft 38 may be preloaded with such clips, which are maintained in a "open" position using a restraint. When the restraint is removed, the clips close and attach to a nearby tissue.

Alternatively or additionally, the graft may be navigated into the pericardium and along the heart. Alternatively, the graft may enter the pericardium only at a point near the point 28 on vessel 22.

Once tip 37 is near coronary vessel 22, an "end-game" step is performed, whereby tip 37 is preferably properly inserted into vessel 22, as shown for example in Fig. 2F, so that graft 38 can be connected to vessel 22. In a preferred embodiment of the invention, an ultrasound imager on guide-wire 36 is used to guide tip 37 to the correct location. Alternatively or additionally, methods as described in the "Transvascular applications", in the background, may be used.

In a preferred embodiment of the invention, connector 40, in its closed position, serves the functions described above for tip 37. In a preferred embodiment of the invention, tip 37 comprises a screw, which is screwed into vessel 22, to create a hole 39 in vessel 22. Alternatively or additionally, a stabilizing tool is guided over guidewire 36, to stabilize vessel 22 relative to tip 37. In a preferred embodiment of the invention, the stabilizing tool is a suction device which attaches itself to vessel 22. Preferably, tip 37 is guided through the suction device. Alternatively or additionally, the stabilizing tool includes a tip having a cross-section which matches the cross-section of coronary 22, at a desired approach angle. Alternatively or additionally, the stabilizing device comprises jaws which grab vessel 22. Preferably, the jaws pinch vessel 22, so that a desired entry point for tip 37 is adjacent tip 37. Preferably, vessel 22, in its pinched configuration presents a narrow aspect to tip 37 and a wide aspect perpendicular thereto, so there is less danger of perforating both sides of vessel 22. Alternatively or additionally, the wide aspect is presented to tip 37, to make aiming easier. Such aiming preferably uses an imager and/or a Doppler sensor to detect the location of flow in vessel 22.

In Fig. 2G, graft 38 is advanced to hole 39 and/or a portion of anastomosis connector 42 is inserted into hole 38. A balloon is preferably guided along guide wire 36 and inflated inside connector 42, so that it expands the anastomosis connection and creates an attachment between vessel 22 and graft 38. Preferably, the balloon is tapered so that it more easily inserted into connector 42. Alternatively or additionally, connector 42 elastically increases in diameter, once it is placed into hole 39 and a restraint removed, to allow enough space for the balloon. Alternatively or additionally, two balloons are used, a narrow one which partially inflates the connector and a wider balloon which completes the inflation of the connector. The leading end of graft 38/connector 40 are preferably tapered, so that they are more easily guided into vessel 22. Alternatively or additionally, guide wire 36 is inserted into vessel 22 for a considerable

distance and/or bent, so that there is less chance of guidewire 36 inadvertently leaving vessel 22.

The result, as shown in Fig. 2H is that graft 38 bridges aorta 30 and vessel 22.

Alternatively or additionally to end-to-side anastomoses at the coronary end illustrated in Fig 2H, side-to-side anastomoses may be used, as described for example in the "Transvascular applications". Fig. 2I shows an example of such connections, where a single graft 38 is attached to two, possibly different coronary arteries 22. The end of graft 38 is preferably blocked and or is used for an end-to side or an end-to-end anastomosis. Alternatively or additionally, graft 38 is prepared so that it does not have a distal opening. When side to side anastomoses are performed, graft 38 may have performed holes in its side or holes may be made during the connection process.

Alternatively or additionally, the navigation, the final alignment with the artery and/or the anastomosis to the artery (e.g., suturing) may be performed using a key-hole surgery technique. It should however be appreciated that key-hole surgery is aided by using the above described technique to bring, to a location adjacent a coronary vessel, a graft, one end of which is already attached to the aorta. Thus, only a key-hole at the anastomosis location is required.

In a preferred embodiment of the invention, after the bypass is performed, the graft is tested for leakage. Preferably, a contrast media is injected and a fluoroscopic image is acquired after a short wait to determine if any of the contrast material has leaked from the vascular system. In case of such leaks, the anastomosis may be strengthened, in some preferred embodiments of the invention, by inflating a balloon inside a leaking anastomosis connector to increase its contact with the wall of the vessel to which it is connected. Alternatively or additionally, a stent and/or a graft may be inserted within the leaky connector so that it is situated between the connector and the blood flow. Alternatively or additionally, the leaking anastomosis may be repeated, by disconnecting the graft from the vessel, providing a suitable anastomosis connector and activating the provided connector, to create the anastomosis. Alternatively or additionally, key-hole surgery is performed only at the leaking anastomosis, for example, to suture it.

Many variations on the technique described above may be performed, within the scope of preferred embodiments of the invention. In the above description, tip 37 punches a pinhole in aorta 30 and vessel 22. Alternatively, tip 37 may be used to punch a hole of a desired size and/or cross-section, in aorta 30 and/or in vessel 22. In a preferred embodiment of the invention, the hole is smaller than the final anastomosis cross-section. Alternatively, the hole is of approximately the same diameter.

The above technique may also be used to connect other blood vessels, for example, for femoral bypass and venous-arterial shunt. In addition, other body lumens may be connected, for example, the intestines, the urinary tract, billiary, and/or respiratory system.

It should be appreciated that guide wire 36, even after it perforates the aorta, does not necessarily allow blood to leak from the aorta. Thus, in some preferred embodiments of the invention, the above technique may be practiced, even if catheter 34 does not isolate hole 35 and/or without stopping the heart and/or without reducing the systemic and/or local blood pressure. Alternatively or additionally, it may be desirable to reduce the risk level so one of the above techniques of reducing leakage from hole 35 and/or reducing the availability of blood at hole 35, may be practiced.

The description of Fig. 2A suggests the desirability of using a "J" shaped catheter and/or pointing the guide wire in the direction of target point 28. However, it should be appreciated that graft 38 is navigated in the body, possibly around obstacles (such as the heart itself). Thus, the initial direction of the guide wire exiting the aorta may be decided by other considerations, such as the location of the graft along the aorta, the ease of repairing the anastomosis, interaction of the anastomosis size, location and angle with blood flow in the aorta and in the graft, and/or plaque location and arteriosclerosis of the aorta. Once the vessel is outside the aorta, it can be guided to point 28.

In a preferred embodiment of the invention, a desired layout of graft 38 is determined before starting the procedure. Such a layout depends not only on the desirability of the end points, but also on the available maximum length of graft 38, the desire to minimize its length, locations to attach the graft to anatomical structures, a desire to minimize the possibility of kinks and/or sharp bends in the graft, a desire to minimize the possibility of the graft getting pinched between two anatomical structures and a desire to minimize the probability of the graft being pulled out of one of the blood vessels it is attached to.

In a preferred embodiment of the invention, as shown in Fig. 2I, graft 38 may be used for a plurality of bypasses, for example, to bypass the entire left anterior descending coronary artery, especially if it has multiple occlusions. In a preferred embodiment of the invention, this is achieved using a plurality of side-to-side connections. Alternatively or additionally, graft 38 may be forked or contain other types of intersections allowing various legs of the graft to be attached at different places. Alternatively or additionally, a second graft 38' may be pushed out of graft 38, after graft 38 is in place, possibly using the techniques described herein. Alternatively or additionally, a side-to end anastomosis may be performed between the two grafts either before or after the first graft is inserted into the body. Alternatively or

additionally, a side-to-side anastomosis is performed. When the second artery is at the "side" side of the anastomosis, the two ends of the second graft are preferably pushed out of the first graft together, until an anastomosis connector attached to the graft reaches the hole through which the graft was pushed out. Then, the anastomosis is preferably performed. It should however be appreciated that the procedures described herein may be applied substantially to any coronary artery.

As described herein, graft 38 is preferably provided through a blood vessel. In an alternate preferred embodiment of the invention, graft 38 is provided using other body organs as passageways, for example, using the lungs, intestines or other hollow organs. Alternatively or additionally, the graft is provided via the body cavity itself, for example, it is pushed into the body from the outside, via hole in the skin. In these embodiments, both of the anastomoses are preferably performed from the graft into a target blood vessel. The guide wire is preferably brought into the graft from a hole near its center and selectively guided to an end, depending on the end to be grafted. Alternatively or additionally, the anastomoses are performed by attaching two grafts, one to each target tissue and then performing an end-to-end anastomosis on the free ends of the two grafts. Such an anastomosis may be performed precutaneously, for example by providing a catheter through one of the target vessels. Alternatively or additionally, the end-to-end anastomosis may be performed using key-hole approach. It should however be appreciated that a precutaneous approach is usually preferably even to key-hole surgery, since it causes even less trauma to the body. However, in some cases, a key-hole surgical procedure is required anyway, so that it may be aided by a precutaneous procedure. Alternatively or additionally, to a key-hole procedure, a transvascular procedure may interact with an endoscopic procedure, whereby a flexible endoscope is guided to a desired location in the body, adjacent where a transvascular procedure is being performed.

In a preferred embodiment of the invention, guide wire 36 has a tip diameter of, for example, 0.018 inches and tapes slightly. When inserting the guidewire into vessel 22, preferably one, two or three centimeters are inserted into the vessel. The anastomosis connector is for example about 0.8 mm in outer diameter, in its closed position and is made of stainless steel at a thickness of between 0.1 and 0.2mm.

The above description is generally applicable with respect to the various types of anastomosis devices used, in accordance with preferred embodiments of the invention, to connect graft 38 with vessel 22 and/or aorta 30. There are several considerations in selecting a configuration for an anastomosis device, some of which are listed below. It should be

appreciated that some of the considerations are taken into account in a positive manner by more of the preferred embodiments than other considerations.

(a) Bringing the two vessel together. In some preferred embodiments of the invention, the anastomosis device brings the two vessels closer together.

(b) Non-desirability of leaks. In some preferred embodiments of the invention, the anastomosis device provide a large area of contact between the two blood vessels, preferably completely surrounding the anastomosis connection. Thus, the probability of leaks occurring is reduced. Alternatively or additionally, the connection may be strengthened after the anastomosis connector is in place, in accordance with some preferred embodiments of the invention.

(c) Non-desirability of vessel flaps remaining in the blood flow. In some preferred embodiments of the invention, such flaps are trapped by the anastomosis connection. Alternatively or additionally, the flaps are pushed out of the blood flow. Alternatively or additionally, such flaps never come into existence, since the anastomotic connections are made by stretching a pin-hole, not by cutting a cross. A cross shaped slit or a straight-line slit may be cut using a guide wire with a suitably shaped tip. Alternatively or additionally, a sharp tip of the guide wire may be used to cut any desired shape by moving it along the surface of the blood vessel.

(d) A requirement to maintain a minimum cross-section of the anastomosis connection. In a preferred embodiment of the invention, the anastomotic connector comprises a ring portion, which maintains the connection cross-section at at least the inner diameter of the ring. Alternatively or additionally, the connection between the two blood vessels is such that the configuration is not under tension or is under a minimal amount of tension when the anastomosis is open. For example, if the lips of the (expanded) pinhole are folded back the tension is much greater on the lips than if they are not folded back. Alternatively or additionally, the blood pressure maintains the anastomosis open. The fact that the anastomosis is on a major blood vessel, in accordance with some preferred embodiments of the invention, aids in keeping it open. Alternatively or additionally, a portion of the "side" vessel is cut out, so that there is an opening therein which is covered by the "end" vessel.

(e) Desirability for a minimum amount of contact of non-endothelial surfaces with the blood. This consideration includes both a desire to minimize the contact between foreign objects and the blood flow, and a desire that after the anastomosis is complete only endothelial surfaces of the blood vessels are in contact with the flow. Various connectors in accordance

with preferred embodiments of the invention, as described herein, meet one or both considerations.

(f) Probability of connection remaining leak proof for a long time. In a preferred embodiment of the invention, the anastomosis connector provides a tissue-to-tissue contact area, in which there is little or no tissue necrosis. Thus, after a short while, a bridge is formed between the tissues of the two vessels.

(g) Requirement to perform eversion of vessel tips, especially if vessels are hardened or otherwise sensitive. Some types of anastomosis require a 90 degree or a 180 degree eversion of the vessels. Although this usually results in a best connection, it may not be possible in some cases, for example if the vessels are hardened or prone to cracking. Some of the anastomosis connectors described herein allow little or no eversion. An additional benefit of not requiring eversion is a reduction in the difficulty in preparing the vessels for anastomosis. Preferably, only the graft vessel is prepared prior to the procedure. The intra-body vessels cannot usually be prepared for anastomosis using precutaneous tools and in some preferred embodiments of the present invention, need not be prepared.

(h) The number of pieces inserted into the body. There is usually a desire to minimize the number of object inserted into the body and/or the blood stream, to minimize the danger of one of the pieces getting lost or stuck. In some preferred embodiments of the invention, the anastomosis connector comprises a single piece, which is pre-attached to the graft. Other embodiments utilize two or more pieces.

(i) The simplicity and speed of performing the anastomosis. In a preferred embodiment of the invention, the speed and simplicity of the anastomosis procedure are improved over those used in the prior art.

(j) The type of connection between the blood vessels. Various types of connections are provided in accordance with preferred embodiments of the invention, as described above and as described below with reference to Figs. 3A-3O. In particular, in some preferred embodiments of the invention the anastomosis connection is an intima-to-intima connection.

(k) The type of force holding the vessel together. Various attachment means are provided in accordance with preferred embodiments of the invention, including, mechanically pushing the two contact surfaces together, for example utilizing pins piercing both surfaces, glue, welding and/or plastic flowable material provided at and/or around the anastomosis connection.

(l) The strain on the blood vessel. The strains are mainly a result of a blood vessel being maintained in an unnatural configuration as a result of the anastomosis. In a preferred

embodiment of the invention, the type of strain may be traded off with the type and/or quality of the connection. For example, strain may be a result of eversion. In a preferred embodiment of the invention, no eversion is require, or eversion may be limited only to a blood vessel which can take the strain. In another example, strain may be the result of stretching a pinhole in a "side" connected vessel. In a preferred embodiment of the invention, a larger hole may be made in this vessel to reduce the strain. In addition, strain may be a result of bending a blood vessel. Various types of bends are provided for in Figs. 3A-3O. In a preferred embodiment of the invention, some of the strain is carried by the anastomosis connector itself. Preferably, the connector is attached to the vessels at many points, so that the strain may be divided over all the connections. In addition, if one connection fails, this does not necessarily mean the anastomosis will leak. Another type of strain is the result of the contact area being substantially non-planar, as for example in a diagonal connection or in an end-to-side connection between two vessels of similar diameters. Preferably, the connector achieves a non-planar shape to conform to the shape of the contact area, thereby minimizing the tension on the vessels. Alternatively or additionally, the graft is precut to have a non-flat end, so as to reduce the strain on it.

In some cases, the long term strain is minimized. Alternatively or additionally, the strain applied during the anastomosis is minimized. Alternatively or additionally, a tradeoff is achieved by which an acceptable strain is present. Preferably, the type of anastomosis performed takes into account a maximum desired strain threshold.

(m) The requirement to provide the anastomosis connector through a narrow-diameter catheter lumen. In a preferred embodiment of the invention, the connector is expandable and/or distortable, so that it may be conveyed in a configuration which fits a desired lumen size. Alternatively or additionally, the connector comprises a plurality of staples or other local connectors and the connection is made using an expandable anvil or framework which is brought through the lumen and expanded to have a diameter larger than the cross-section of the anastomosis. Alternatively or additionally, the minimum diameter of the graft with the connector attached may also be controlled and is different for different types of connectors and/or connection configurations. For example, configuration 82 in Fig. 4B can have a smaller diameter than configuration 80.

(n) Turbulence. The connection between the two blood vessels may cause turbulence, stagnation and/or clotting. In a preferred embodiment of the invention, the angle and/or size of the anastomosis is selected to minimize turbulence. Alternatively or additionally, a connector

type and/or an anastomosis type is selected to minimize turbulence, for example, by providing a low profile anastomosis connection.

(o) Blockage of the graft or the end-vessels. In a preferred embodiment of the invention, most or all of the anastomosis connection is outside the blood vessels, so that the flow of blood in the anastomosis area is minimally impeded. Alternatively or additionally, in large blood vessels, a small portion of the cross-section may be sacrificed to achieve a better, faster and/or lower cost anastomosis.

Figs. 3A-3O illustrate different types of side to end and end-to end joints, achievable in accordance with preferred embodiments of the invention. Figs. 3A-3H describe end-to-side anastomoses. Figs. 3I-3O describe end-to-end anastomoses. Typically, an anastomosis connector, as described bellow will either pierce the blood vessels on both sides of the contact area or will follow the contour of the contact area. Alternatively, the connector may be completely outside the blood vessels.

Fig. 4A illustrates a one piece anastomosis connector 60, in plan view, in accordance with a preferred embodiment of the invention. Connector 60 preferably includes a first spike section 64, a central section 61 and a second spike section 66. Preferably, the central section comprises a plurality of parallelograms 62. When installed, central section 61 is preferably closed, for example, by overlapping at the two lines marked "A". This closing may be by manual welding, supplying a connector or by connector 60 being formed as a cylinder. Alternatively or additionally, connector 60 is formed to naturally assumes a cylindrical shape. Alternatively or additionally, connector 60 is simply rolled into a cylindrical shape, without the two sides being connected.

In a preferred embodiment of the invention, all the parallelograms 62 are of equal size. Alternatively or additionally, they are not all the same size and/or shape. In a preferred embodiment of the invention, section 61 comprises bands, each of which has a different parallelogram size and/or shape. The bands may be radial. Alternatively or additionally, the bands are axial. Alternatively or additionally, a different spatial distribution of parallelograms is used. The spikes may be connected at outer vertexes 72 of section 61. Alternatively or additionally, some or all the spikes of at least one of the sides are connected to inner vertexes 74. The ratio between an axial radius 70 and a radial axis 68 of the parallelogram is preferably a controllable property of the device.

Connector 60 may be formed to have elastic tensions in portions thereof so that it has a resting shape other than that of a cylinder. Preferably, connector 60 comprises a super-elastic material. While being deployed, connector 60 is preferably maintained in a desired form using

mechanical restraints. Alternatively or additionally, connector 60 is formed of a shape-memory alloy, which is activated when the connector is deployed. Alternatively or additionally, at least portions of connector 60 are formed of a plastic material, which is plastically distorted, for example by a balloon, into a desired configuration. These different elastic characteristics may be combined in a single device. For example, the spikes may have a super elastic tendency to fold out and grab tissue, the cylinder may be super elastic, so that when relived of constraints, it expands radially slightly, thus providing room for a balloon to be inserted therein. The rest of the deformation is preferably provided by plastic deformation. Alternatively or additionally, some portions of connector 60 may be specifically made weaker so that any plastic deformation tends to concentrate at those locations. Thus, it is possible to predetermine where connector 60 will bend, when inflated.

In a preferred embodiment of the invention, the maximum radial expansion in the center of the connector is smaller than at it upper or lower (axial) ends. Thus, when inflated it will assume an hour-glass form. Such a form may also assist in everting the tips of the graft and/or the aorta. Alternatively or additionally, the connector is made stiffer at its center, so that when inflated by an elastic balloon, it will tend to inflate more at its ends that at its center. In a preferred embodiment of the invention, different levels of stiffness may be achieved by varying the shape of the parallelograms and/or the thickness of the sides and/or by surface treating portions of the connector and/or by heat-treatment of portions of the connector and/or by using special coatings on portions of the connector.

In a preferred embodiment of the invention, the connector is not symmetrical in its final configuration, around an axial axis and/or around a radial axis. In one example, the lower portion has a maximal radial expansion higher than the upper portion. In a preferred embodiment of the invention, this asymmetry is made to match characteristics of the connection type and/or the relative sizes of the blood vessels. In a preferred embodiment of the invention, the parallelogram's sizes and stiffness is varied so that the connector everts over itself, possibly 90 or 180 degrees and/or assumes the shape of a top-hat, with a "T" cross-section". This type of connector may be used as a "T" shaped patch to patch up a failed side-to-end anastomosis. Alternatively or additionally, this type of configuration is used for everting a "side" end of an anastomotic connection.

In a preferred embodiment of the invention, other hole shapes besides parallelograms are used, for example, other four-sided shapes, pentagons, hexagons, circles and/or arbitrary shapes formed of straight lines and/or curved lines. In a preferred embodiment of the

invention, a triangular shaped hole is used, preferably one of the side of the triangle is pre-formed so that when it is distorted it folds out to engage tissue and not into the blood stream.

In a preferred embodiment of the invention, connector 60 is radioactive, preferably, to retard intimal growth. Preferably, the level of radioactivity is not constant along the length of the connector. Preferably, portions of the connector which are at or near the contact between the two blood vessels are not radioactive. Alternatively or additionally, only portions of the connector which are in contact with the blood are radioactive. Alternatively or additionally, the spikes are not radioactive, at least in portions thereof which engage the vessel walls.

Alternatively or additionally, the resting form of connector 60 is not a simple cylinder. In a preferred embodiment of the invention, the connector naturally assumes a form shown by cross-section in Fig. 4B, below.

One characteristic of some preferred embodiments of the connector shown in Fig. 4A, is a coupling between radial expansion an axial contraction. In a preferred embodiment of the invention, when connector 60 is expanded in a radial direction, it contracts in an axial direction. An example of this relationship is illustrated in Figs. 4B-4D which show different amounts of radial expansion.

Fig. 4B shows in cross-section two possible starting configurations, 80 and 82, for mounting a connector 60 on a graft 38. In both configurations, spikes 66 are bent and spikes 64 are bent to engage the graft. However, in configuration 80, spikes 64 conform to the eversion of the graft, while in configuration 82, spikes 64 pierce through the everted portion of the graft. Typically only one of configurations 80 or 82 will be used in any particular connection. In some cases however, both configurations may be used in a single connector.

In Fig. 4C aorta 30 is shown in cross-section, whereby it is not yet engaged by spikes 66. This configuration is preferably achieved by pushing the configuration of Fig. 4B out of the aorta, along a guide wire, until the everted part of graft 38 comes into contact with the aorta, as shown in Fig. 4C.

In Fig. 4D, a balloon is expanded inside graft 38. As a result, the inner radius of connector 60 increases. Simultaneously, the hole in aorta 30 is also expanded. Also simultaneously, connector 60 experiences an axial contraction, which urges spikes 66 into the aorta and which forces together the everted portion of graft 38 and aorta 30. In this anastomosis two surfaces which are forced into contact are indicated in Fig. 4D as 84 and 86 respectively, namely (i) the aorta and the side of the graft and (ii) the inside of the aorta and the everted portion of the graft. Although connector 60 runs along one (configuration 82) or

both(configuration 80) of these surfaces, there is a large amount of tissue-to-tissue-contact, since the connector is preferably not a solid surface.

In a preferred embodiment of the invention, connector 60 has a non-constant thickness. In a preferred embodiment of the invention, the non-constant thickness is used to provide varying amounts of elasticity and plasticity to different parts of the connector. Alternatively or additionally, increases in thickness, for example as shown at locations 88 in Fig. 4D, possibly comprising a ring around the connector, are used to provide a better seal against blood escaping the anastomosis.

Fig. 5 is a graph illustrating various possible relationships between radial expansion and axial contraction in anastomosis connector 60. As shown in Fig. 5, both positive and negative couplings are possible. In addition, the coupling may be dependent on the instant radius of the connector. Thus, in a fully inflated configuration, additional inflation will not provide much additional axial contraction. A reference number 85 indicates a positive, decreasing coupling, where increasing the diameter increases the axial dimension, however, to a lessor degree as the radius increases. A reference number 87 indicates a negative, constant relationship, whereby increase in radius always decreases the axial dimension. A reference number 89 indicates the coupling described above, whereby a large axial shortening is achieved when the radius is small and a small axial shortening is achieved when the radius is large. References 81 and 83 indicate non-monotonic coupling, where the decrease in axial dimension is relatively constant over a "working range" of the device.

In a preferred embodiment of the invention, the spikes are not straight (as shown in Fig. 4A). In a preferred embodiment of the invention, the spikes are tapered over a considerable portion of their length. Alternatively or additionally, the spikes are jagged. Alternatively or additionally, the spikes have an inverse taper or are barbed, so that they are more difficult to remove. Alternatively or additionally, instead of spikes, the "spike" portion is a relatively continuos surface, such as a band, which surface can evert in a manner similar to a rivet. And thereby engage the blood vessels.

Figs. 6A and 6B illustrate an alternative one piece anastomosis connector 90, in accordance with a preferred embodiments of the invention. In Fig 6A the connector is shown in plan view, in a compressed configuration. Dots 92 indicate short pikes which are preferably used to engage the blood vessels. In a preferred embodiment of the invention, however, the connector will be attached to graft 38, as shown in Fig. 6C, prior to inserting the graft into the body.

When inflated and/or allowed to return to a resting condition, some of the spikes and the band to which they are attached fold up and some fold down, resulting in the configuration of Fig. 6B, which illustrates connector 90 in its final configuration. Figs. 6C-6E illustrate a method of achieving this configuration.

In Fig. 6C, connector 90 is mounted on a graft 38. A plurality of inner arms 96 are inside the graft, a plurality of spikes 94 on the arms do not engage tissue and the graft itself is not everted. The arms may comprise substantially rectangular pieces. However, In a preferred embodiment of the invention,, the arms comprise a Gaussian-like (or half-sine-wave) portion of metal which has a spike at its tip. Thus, connector 90 preferably has a smooth outline. In Fig. 6D, the graft is expanded, for example using balloon or relaxing a constraint on a super-elastic connector 90, so that arms 96 bend out and the graft becomes everted. In Fig. 6E, either the expansion is continued or connector 90 is squeezed against a balloon, so that spikes 94 engage the aorta. Connector 90 may be squeezed for example, by providing one balloon on each side of the connector and inflating the balloons. Alternatively or additionally, the body of catheter 34 may provide an anvil against which connector 90 is compressed.

In the example of Figs. 6A-6E, the connector supports a multi-step connection process, in which each additional inflation further modifies the shape and/or configuration of the connector and advances a step of the connection, i.e., engaging the graft, everting the graft and finally engaging the aorta. Each one of these steps may be mediated by a different part of the connector.

In a preferred embodiment of the invention, a different type of connector is provided, formed of a soft material, for example silicone. This connector comprises a tubular portion, which engages either the inside or the outside of the graft and one or more leaves which fold out against the inside of the aorta. In a preferred embodiment of the invention, these leaves include barbs which engage the aorta. Alternatively or additionally, the tubular portion includes a depression which engages the cross-section of hole 35 (Fig 2). Alternatively or additionally, the tubular section includes a ring, embedded in the soft material, which maintains the cross section of the hole 35 and/or in which the depression is formed, so the connection does not slip. In some embodiments, no leaves are required.

In a preferred embodiment of the invention, the soft material comprises a graft material, preferably a biological graft material, inside of which an expandable ring is embedded. Alternatively or additionally, the graft is everted 180 degrees over such a ring. The everted portion of the graft is inserted into the hole in aorta 30 in a compressed form and when

it is expanded it opens the hole and the graft-covered ring engages the walls of aorta 30, in a groove along the outer rim of the ring.

Figs. 7A-7B illustrate a pin based ring anastomosis connector 100, in accordance with a preferred embodiment of the invention. Fig. 7A shows connector 100 in a radially compressed configuration. Dots 102 indicate spikes. Connector 100 may be used by itself to affect anastomosis Alternatively or additionally, connector 100 may be used with a second, possibly similar ring. Fig. 7B shows connector 100 after it is deployed, in conjunction with a second ring 108. Spikes 104 of ring 100 engage pre-formed holes 106 in ring 108. Alternatively or additionally, spikes 104 may be longer than shown and fold back after piercing graft 38 and aorta 30. Thus, a second ring may not be required. Preferably, the rings are folded back against an anvil, for example an inflatable balloon or a collapsible ring structure which is urged against the spikes for bending them and then removed from the body.

In a preferred embodiment of the invention, both rings 100 and 108 include spikes and pre-formed holes. Alternatively or additionally, at least one of the rings has only spikes or only holes. Alternatively or additionally, to holes 106, ring 108 may have formed therein a groove or a plurality of closely-set holes which spikes 104 may engage w/o aligning the two rings. Alternatively or additionally, spikes 104 engage a piercible friction material, such as silicone, which holds the spikes, for example by friction, instead of or in addition to holes 106. The entire ring or portions thereof may be formed of the friction holding material Alternatively or additionally, the friction holding material may comprised in a layer on top or below a non-piercible portion of the ring. In a preferred embodiment of the invention, spikes 104 are jagged, to better engage the friction material.

Figs. 8A-8D illustrate a method of performing an anastomosis in accordance with a preferred embodiment of the invention. In Fig. 8A, a graft 38 is guided along a guide wire 36 through a hole 118 and out of the aorta. A friction ring 120 is attached to a preferably everted portion 116 of the graft. Preferably, a tapering 114 is provided to ease the exit of the graft from the aorta. A ring 110 with pins 112 is shown positioned further proximally along guidewire 36. Alternatively, the ring with the pins may be on the graft and friction ring 120 be further along guide wire 36. Alternatively or additionally, no friction ring is provided and pins 112 will engage only graft 38 and preferably fold back. In Figs. 8A-8C, the graft and the anastomosis connectors are preferably in a compressed configuration. Alternatively or additionally, the connectors are expanded before inserting attaching ring 110 to ring 120.

In Fig. 8B, graft 38 is outside aorta 30 and is preferably pulled back against the aorta, for example by pulling back guide wire 36. Ring 110 is pushed forward so that pins 112 pierce

aorta 30, graft 38 and friction ring 120. In a preferred embodiment of the invention, ring 120 is pushed by inflating a balloon on guide wire 36, just proximal to ring 110, so that the inflation of the balloon pushes the ring forward. Alternatively or additionally, a second balloon may be inflated on the other side of ring 120, to urge ring 120 towards ring 110. Alternatively or additionally, one or both of these pushing forces are applied by pulling wires coupled to graft 38 and rings 110 or 120.

In Fig. 8C, the anastomosis is nearly complete, however, an opening 118 is not yet expanded. In Fig. 4D, the opening is expanded and the anastomosis is complete. Opening 118 may be created by making one or both of rings 110 and 120 of a super elastic material and by reliving a constraint which maintains them in a compressed configuration. Alternatively or additionally, a balloon may be inflated in opening 118 to plastically deform the anastomosis connection. Alternatively or additionally, the same balloon used for urging the rings together may be further inflated, to expand the opening. In a preferred embodiment of the invention, the balloon has two inflation levels, a first inflation level at which the balloon urges the rings towards each other and a second inflation level at which a more distal portion of the balloon expands radially. Alternatively or additionally, the balloon is deflated after urging the rings together, advanced into opening 118 and re-inflated to expand the opening.

It should be appreciated that similar methods may be used in conjunction with a ring connector which does not use a second ring and in which the spikes are folded back by pushing them against an anvil. A balloon would then preferably perform the function of an anvil. Alternatively or additionally, the balloon expands an anvil which then collapses when the balloon is deflated.

Fig. 8E illustrates a friction ring in accordance with an alternate preferred embodiment of the invention. Views 1-3 show the ring in a side view and in cross-sectional views, when the ring is collapsed. In view 4, the ring is unfolded and has a larger diameter. Portions "A" and "B" interleave to form a single ring which is folded such that a top layer comprises of portions "A" and a bottom layer comprises of portions "B". In a preferred embodiment of the invention, the spikes of ring 110 are inserted into portions B of the ring, in Fig 8B above.

In a preferred embodiment of the invention, the friction ring may include a plastic or a super-elastic stiffener, so a stiff ring is required only on one side of the anastomosis. Alternatively or additionally, neither side comprises a stiffener, rather, both are relatively flexible.

Figs. 8F-8I illustrate different relative placements of the ring(s), aorta 30 and graft 38, in accordance with preferred embodiments of the invention. In Fig. 8F, ring 110 is in the aortic

blood flow. In addition, an aortic flap 124 may be left dangling as a result of creating the hole in the aorta. In a preferred embodiment of the invention, such an aortic flap is pushed put with graft 38 and is then trapped by spikes 112 and/or by the pressure between rings 110 and 120 (shown as flap 124'). In a preferred embodiment of the invention, ring 120 is wider than everted portion 116 of graft 38. Thus, ring 120 may form an external seal against aorta 30. Preferably, ring 120 includes a depression to accommodate everted portion 116, so that the outer portion of ring 120 is flush against the aorta. In a preferred embodiment of the invention, ring 120 includes short spikes to which everted portion 116 is attached. Alternatively or additionally, ring 120 includes a ridge facing ring 110.

In Fig. 8G, everted portion 116 of the graft is inside the aorta. In a preferred embodiment of the invention, silicon ring 120 is not preloaded on everted portion 116, rather ring 110 is so preloaded. To perform the anastomosis, ring 120 is preferably pulled back (or pushed back) onto spikes 114, preferably using a balloon on the outside of graft 38. Alternatively or additionally, the balloon is inflated inside graft 38, to hold ring 120 from inside the graft..

In Fig. 8H, everted portion 116 is also inside the aorta. However, ring 110 is now between the aorta and everted portion 116. In a preferred embodiment of the invention, ring 110 includes short spikes 122 which engage everted portion 110. Alternatively or additionally, ring 110 is glued or otherwise attached to everted portion 116. In a preferred embodiment of the invention, ring 110 includes a sealant material which seals the gap between everted portion 116 and aorta 30. Alternatively or additionally, ring 110 includes a coating which induces blood clotting and/or tissue bonding at the connection. In a preferred embodiment of the invention, no ring 120 is used. Rather, spikes 114 bend back upon themselves after they pierce aorta 30, in a manner indicated above.

In a preferred embodiment of the invention, preferably where no ring 120 is used, spikes 114 are preferably super-elastic and have a resting state whereby the spikes are bent at or near their base. In a preferred embodiment of the invention, spikes 114 are maintained at a straight configuration using a thin framework which fits between everted portion 116 and aorta 30. Once the pins pass through the aorta, the framework is removed, allowing the pins to fold back and/or to bring together everted portion 116 and aorta 30.

In Fig. 8I everted portion 116 is everted by 180 degrees, so there is no non-endothelial contact between the anastomosis connector and the blood. In addition, only smooth surfaces are presented to the blood (no ragged edge of graft 38), so there is less chance of turbulence. In a preferred embodiment of the invention, after the anastomosis is completed, the connector is

pushed out of the aorta, preferably using a balloon, so that the entire connector is outside both blood vessels, for example as in Fig. 3G, with the connector outside the protrusion of the anastomosis.

In a preferred embodiment of the invention, the connection between the rings is provided by magnetic force, for example as described in "Non-suture micro-vascular anastomosis using Magnet rings: Preliminary report", by Obora Y., Tamaki N. and Matsumoto S., in Sur Neurol (UNITED STATES) Feb 1978, 9 (2) p 117-120, ISSN 0090-3019, the disclosure of which is incorporated herein by reference. In a preferred embodiment of the invention, the rings comprises a magnetic material. Alternatively or additionally, only rigid parts of the rings are magnetic and are situated or held within or between non-magnetic, more elastic parts. Alternatively or additionally, only one of the rings is magnetic, with the other ring preferably being ferromagnetic. Preferably, the magnetic portion is extra aortic, so that it does not impede flow. Alternatively or additionally, a magnetic force may be used to bring the two rings together, even if the maintenance of the connection is mechanical. In one example, indicated above, one ring is magnetic and the other is ferromagnetic. In another example, a magnetic force is applied from outside the body, for example using a large electro-magnet. Alternatively or additionally, the two rings are magnetized so that they automatically align in a desired relative orientation, for example, so that spikes and holes line up.

In some of the above described embodiments, the ring performs two functions, namely aligning the spikes with the tissue to be pierced and maintaining the anastomosis opening. In addition, the ring exerts pressure along its entire circumference, not only where there are through spikes. In some anastomosis connections, some of these functions are not required and/or may be performed without a ring. In one example, if a round opening is cut in the aorta, there is no need to maintain the opening size. In another example, if the spikes are close enough together and/or in other situations, there will be no leakage, even if the ring does not apply pressure along the entire circumference of the anastomosis. In a preferred embodiment of the invention, the alignment function is performed by a framework which is removed after the anastomosis is completed. Thus, the completed anastomosis comprises a plurality of spike connectors without a stiffening ring. In a preferred embodiment of the invention, the spikes remain interconnected by a flexible connector, such as a silicone ring. Alternatively or additionally, the spikes are not interconnected. In a preferred embodiment of the invention, such a framework comprises an anvil against which the spikes are bent. Alternatively or additionally, the framework comprises a ring which is removed from the spikes after the spikes are inserted.

Fig. 9A illustrates a sleeve attachment 130 for a graft 38, in accordance with yet another preferred embodiment of the invention. In many cases everting graft 38 may damage the graft. In a preferred embodiment of the invention, a sleeve attachment 130 is everted over a ring 110 and then attached to graft 38. Alternatively or additionally, the sleeve is first attached to the graft and then everted over the connector. In a preferred embodiment of the invention, sleeve 130 comprises a blood vessel segment which has a larger inner-diameter than graft 38. In a preferred embodiment of the invention, sleeve attachment 130 is glued to graft 38. Alternatively or additionally, the attachment is sutured to graft 38. Alternatively or additionally, it is welded and/or attached using a plastic flowable material.

Figs. 9B illustrates attaching a patch 134 to the outside of a blood vessel 132, using devices and/or techniques as described herein. Although a flat patch 134 is shown, patch 134 may comprises a graft with an end tied off. Preferably, the patch is pushed out of vessel 132, through a hole 133. A connector 136 pulls the patch against vessel 132. Alternatively or additionally, a spike type connector 137 may be used to maintain the patch in contact with the vessel. A connector such as a connector 137 does not maintain hole 133 in an open configuration, so there is usually less strain on vessel 132. In many cases, there will be no leakage through hole 133, even if the patch is not hermetically sealed, due to the elasticity of the walls of vessel 132.

Patching a blood vessel may be desirable if the vessel wall is damaged at that point, to relive strain, for example caused by an anastomosis and/or to support an electrode or a different wire or tube which exits the blood vessel. In a preferred embodiment of the invention, such a patch is applied for a side-to-side anastomosis, either on the outside of vessel 132 or on its inside. Preferably, a single connector is used both for the anastomosis and for the patching.

Fig. 9C illustrates configurations in which patch 134 is inside the blood vessel. In a configuration 138, the connector is situated along the edge of the patch, possibly covering any ragged edges and engages vessel 132. Preferably, the engagement is by pins which pass through the vessel. Alternatively or additionally, connector 138 passes through a hole in vessel 132, as shown for example in Fig. 9B. In configuration 140, a spike pierces both patch 134 and vessel 132. The spike may bend back. Alternatively or additionally, a friction material, such as a ring is provided on the other side of vessel 132, preferably after being pushed out through a hole in vessel 132. In configuration 141, a spike is embedded in- or otherwise attached to- patch 134, so that there is no contact between the connector and the blood flow.

Fig. 9D illustrates a strain reliving device 142, attached to vessel 132, either on its inside or on its outside. In a preferred embodiment of the invention, device 142, shown as a

grid is covered with a graft material. Dots 144 indicate pins which engage vessel 132 itself. In a preferred embodiment of the invention, the pins are super-elastic and are maintained in a configuration where they are pointing away from the vessel wall. When device 142 is positioned in a desired location, a restraint is released and the pins bend to engage the vessel wall. The pins may be distributed evenly over device 142. Alternatively or additionally, the distribution is uneven, preferably to match a strain pattern.

In a preferred embodiment of the invention, device 142 is used to relive strain on a wall of vessel 132. The distribution of pins 144 will usually affect the amount and directionality of the strain in vessel 132. Although device 142 is shown as being substantially planar, in a preferred embodiment of the invention, device 142 may be curved or even cylindrical.

In a preferred embodiment of the invention, device 142 provides a framework for an endoscopic procedure, and as such, it may be inserted outside of the blood stream. Alternatively or additionally, device 142 may include rails or other guidance mechanisms for guiding the procedure. Such rails preferably follow the surface of device 142. In a preferred embodiment of the invention, the rails include junction points or otherwise identifiable points where a guided tool may fix its position relative to the device. In a preferred embodiment of the invention, device 142 may be moved between two or more configurations, for example, by inflating a balloon therein. Preferably, when the device changes configuration, it changes the relative positioning of body tissues which are attached to different parts of the device. When the procedure is completed, the device may be removed by folding it. Preferably, all the pins are bent in such a direction that folding the device retracts them from the tissue. In a preferred embodiment of the invention, the device is folded by engaging it with one or more arms comprising a super-elastic material and relieving a restraint on the arms so that they fold, folding the device with them. Alternatively or additionally, the holding strength of the pins may be reduced if the comprise a super-elastic material which is cooled below its critical point.

Many variations on the above described devices may be practice within the scope of some preferred embodiments of the present invention. In a preferred embodiment of the invention, the connector is smooth, at least in portions thereof that are in contact with blood flow. Alternatively or additionally, the connector is rough or has grooves defined therein, at least in portions thereof which are in contact with blood vessel tissue.

In a preferred embodiment of the invention, the spikes are sharp. Alternatively or additionally, the spikes are blunt. In a preferred embodiment of the invention, the spikes have a flat rectangular cross-section. Alternatively or additionally, the spikes have a triangular or a

circular cross-section. In a preferred embodiment of the invention, not all the spikes have the same cross section and/or sharpness and/or tip shape.

In a preferred embodiment of the invention, spikes are placed close together, so that they can support the anastomosis. Alternatively or additionally, the spikes are relatively few and/or far apart and the anastomosis is supported by rings to which the spikes are connected and which exert pressure on the anastomosis. In a preferred embodiment of the invention, the spikes and/or the rings are arrange in two or more concentric layers, so that a double seal/anastomosis is formed.

It should be appreciated that a single anastomosis connector may include features from different ones of the connectors described above, for example, a connector may include both spikes which hold together the vessel and the graft and a structure which urges the vessel and the graft together.

Much of the above description has centered on the anastomosis connection at the aortic side of a bypass, however, these anastomoses connections may also be applied to the coronary side of the bypass. It should be noted that once the end of graft 38 and the connector attached thereto are inserted into coronary vessel 22, the situation is the same as when graft 38 is inside the aorta, i.e., the graft may be pulled out. However, it should be noted that vessel 22 has a smaller diameter, so a lower profile connector may be desirable. In addition, it may not be desirable to push a large connector out of the aorta to vessel 22. Thus, a smaller connector is preferably used for the arterial end of the graft. Alternatively or additionally, the connector used for vessel 22 may combine the functions of tip 37 and of at least part of the anastomosis process.

In a preferred embodiment of the invention, a failed anastomosis may be removed, either during the attachment process or after it is completed. In one example, if anastomosis at vessel 22 fail, the tip of graft 38 may be cut off and a new anastomosis connector provided along guide wire 36, for connecting at a new point. In some cases the hole in vessel 22 will not leak without any further treatment. Alternatively or additionally, the hole is patched, either as described above or using techniques known in the art, for example, coating it with a flowable material. Alternatively or additionally,, when the graft is cut, the end of the graft near vessel 22 is sealed off.

Figs. 10A-10D illustrate an end-to end anastomosis in accordance with a preferred embodiment of the invention. When provided, an anastomosis connector 152 has a diameter smaller than that of a vessel 150. A balloon 156 is inflated under one end of connector 152, so that it expands radially and spikes thereon engage the walls of vessel 150. A second vessel 154

is then brought to a position where it overlaps the second end of connector 152. When the second end of connector 152 is inflated, it expands radially and preferably also contracts axial. Thus, a better contact is formed between the two blood vessels.

In a preferred embodiment of the invention, connector 152 includes a ridge 153, preferably around most or all the circumference of connector 152. Thus, when the two blood vessels are brought together, the ridge guides an automatic eversion of the two blood vessels. In a preferred embodiment of the invention, the ridge is not continuous and contains holes and/or gaps, so that the two blood vessel surfaces can be in contact through the ridge.

In a preferred embodiment of the invention, connector 152 is used for an externally meditated anastomosis. Preferably, connector 152 is formed of a super elastic material and is constrained to be radially compressed by a device which circles connector 152 at ridge 153. After the two blood vessels are placed on the connector, the restraint is removed and the two blood vessels are automatically engaged by connector 152, advanced towards each other and attached to each other. Possibly, they are also everted over ridge 153.

In a preferred embodiment of the invention, when a graft is implanted and found to be too long, it may be sectioned and the sectioned portions be attached using an end-to-end anastomosis, as described above. Alternatively or additionally, the graft is attached to supporting tissue so that it does not move around.

Fig. 11 illustrates a graft delivery system 201, in accordance with a preferred embodiment of the invention. Referring back to Fig. 2, a "J" shaped catheter 34 includes a lumen through which a guide wire 36 may be provided. The lumen may also be used to perform suction, for collecting debris, to provide other tools, to inject contrast media, drip anti-clotting drugs, to provide saline solution and/or to seal off the work area from the blood flow. Guide wire 36 has a sharp tip 37 which is preferably tapered and which may be used to pierce both aorta 30 and vessel 22. Alternatively or additionally, the guide wires are switched so that different guide wires are used for the different vessels.

A graft 38 is preferably preloaded with anastomosis connectors 202 (aortic) and 204 (coronary), prior to being inserted into the body. Connector 204 preferably includes a tapering surface 206 to ease its insertion into the holes created by tip 37. Alternatively or additionally, a tapering surface 206 may be independently provided over guidewire 36 and retracted when not needed. Preferably, tapering surface 206 is an inflatable tapering and/or otherwise expandable.

In Fig. 11, a narrower connector profile is used for connector 204 than for connector 202. However, this is not a requirement of all the preferred embodiments of the present invention. A balloon 200 is preferably provided over guide wire 36 to expand the connectors.

A second balloon 206 may also be provided. The second balloon may have a narrower cross-section than balloon 206. Alternatively or additionally, balloon 206 may be used in conjunction with balloon 200, to squeeze an anastomosis connector.

In a preferred embodiment of the invention, catheter 34 is not used and graft 38 is exposed to the blood. Some or all of the elements shown in Fig. 11 are preferably disposable. Alternatively or additionally, at least some of the elements are sterilizable, for example, guide-wire 36.

It should be appreciated that imaging devices may be used to track the process of anastomosis, including, the location, the quality of the seal and the relative positions of the tools, grafts and/or connectors. Such imaging devices may be external to the body, internal to the body and/or provided at catheter 34, such as near tip 37. Possible imaging devices include: optical sensors, ultrasound sensor, fluoroscopy, open MRI and CT.

In many of the above described embodiments a balloon is suggested when describing an inflatable member. It should be appreciated that in many embodiments what is required is a framework which can controllably change its configuration, radially or axial, and/or possibly to apply force. In some cases, a continuous surface is required, in others, only the relative positions of certain points on the balloon are important. Other framework types besides balloons are known to provide one or more of these properties and may be used in the above described preferred embodiments of the invention. In some cases, these frameworks will be covered with a flexible covering, to reduce the danger of clotting and/or to be removed after use.

It will be appreciated that the above described methods of vascular surgery may be varied in many ways, including, changing the order of steps, which steps are performed inside the body and which outside, the order of anastomoses, the order of steps inside each anastomosis, the exact materials used for the anastomotic connectors and/or which vessel is a "side" side and which vessel (or graft) is an "end" side of an end-to-side anastomosis. In addition, a multiplicity of various features, both of method and of devices have been described. It should be appreciated that different features may be combined in different ways. In particular, not all the features shown above in a particular embodiment are necessary in every similar preferred embodiment of the invention. Further, combinations of the above features are also considered to be within the scope of some preferred embodiments of the invention. Also within the scope of the invention are surgical kits which include sets of medical devices suitable for a single or a small number of anastomoses.

It will be appreciated by a person skilled in the art that the present invention is not limited by what has thus far been described. Rather, the scope of the present invention is limited only by the following claims.

CLAIMS

1. A method of vascular surgery comprising:

guiding a graft through a vascular system and out the side of a vessel; and

precutaneously and transvascularly attaching at least a first end of the graft to the blood vessel,

wherein said attachment comprises an independently patent anastomosis.

2. A method according to claim 1, wherein said connection is a side-to-side anastomosis.

3. A method according to claim 1, wherein said connection is an end-to-side anastomosis.

4. A method according to any of claims 1-3, comprising connecting a second end of said graft to a second blood vessel, wherein said connection comprises an independent anastomosis.

5. A method according to claim 4, wherein connection comprises transvascularly connecting.

6. A method according to claim 4 or claim 5, wherein said second connection comprises a side-to-side anastomosis.

7. A method according to claim 4 or claim 5, wherein said second connection comprises an end-to-end anastomosis.

8. A method according to any of claims 4-7, comprising connecting another end of said graft to a third or to said second blood vessel.

9. A method according to any of claims 1-8, wherein said second blood vessel comprises a descendent of said first blood vessel.

10. A method according to any of claims 1-8, wherein said second blood vessel is not a descendent of said first blood vessel.

11. A method of vascular surgery, comprising:

providing a first vessel;

providing a second vessel or a graft; and

transvascularly creating an anastomotic end-to-side connection between said vessel and said second vessel or graft.

12. A method according to claim 11, wherein said anastomosis does not require removing portions of said vessel or said second vessel or graft.

13. A method of cardiac bypass surgery, comprising:

creating an anastomotic connection between an aorta and a first end of graft; and

creating an anastomotic connection between a second end of the graft and a coronary artery,

wherein said creating and said creating are performed transvascularly.

14. A method according to claim 13, comprising, navigating said graft from said aorta to said coronary artery, outside of a vascular system.

15. A method according to claim 13 or claim 14, wherein at least one of said connections is a side-to-end anastomosis.

16. A method according to claim 13 or claim 14, wherein at least one of said connections is an end-to-side anastomosis.

17. A method of graft attachment comprising:

providing a graft having a length at least 10 times its diameter;

transvascularly guiding said graft through a vasculature to a first location on a first blood vessel;

attaching one portion of graft to said first blood vessel at said first location; and

attaching a second portion of the graft to a second blood vessel or to said first blood vessel, at a second location.

18. A method according to claim 17, comprising navigating said graft from said first location to said second location.

19. A navigation method comprising:

precutaneously providing a graft at a first location; and

navigating, outside of a body lumen, at least an end of said graft to along a path from said first location to a second location.

20. A method according to claim 19, comprising viewing said path using an ultrasonic imager coupled to said graft.

21. A method according to claim 20, wherein said imager is outside of said graft.

22. A preloaded graft comprising:

a graft section; and

at least one independent collapsible or expandable anastomotic connector attached thereto.

23. A graft according to claim 22, wherein said anastomotic connector comprises a side-to-end connector.

24. A graft according to claim 22, wherein said anastomotic connector comprises a side-to-side connector.

25. A graft according to any of claims 22-24, wherein said connector comprises an everting connector.

26. A graft according to and of claims 22-25, wherein said connector comprises a flap, which flap is attached directly to said graft.

27. A graft according to any of claims 22-26, wherein said graft comprises at least three extensions, through which blood may flow.

28. A method of transvascular anastomosis, comprising:
providing a guide wire tip near a portion of vessel;
precutaneously stabilizing said portion of said vessel; and
inserting said guide wire into said stabilized vessel.

29. An anastomotic connector comprising:
a cylindrical portion; and
a plurality of tissue engaging portions, wherein
radial expansion of said cylindrical portion is coupled to axial contraction of said cylindrical portion.

30. A connector according to claim 29, wherein said cylindrical portion comprises an array of parallelograms.

31. A connector according to claim 30, wherein not all the parallelograms have the same properties.

32. A method of anastomosis attachment comprising:
inserting an anastomotic device to attach two blood vessels; and
inflating a balloon in said device if said attachment leaks.

33. A method of anastomosis comprising:
determining various desired properties of an anastomotic connection; and
selecting an inflatable side-to-end anastomotic connector, responsive to the determined properties.

34. A method of anastomosis comprising:
providing an inflatable anastomotic device; and
inflating said device to simultaneously open an anastomotic passage and perform an anastomotic connection.

For the applicant,

Fenster & Co. Patent attorneys Ltd.
c: 088/00536

ABSTRACT OF THE INVENTION

A method of vascular surgery comprising:

guiding a graft through a vascular system and out the side of a vessel; and

precutaneously and transvascularly attaching at least a first end of the graft to the blood vessel,

wherein said attachment comprises an independently patent anastomosis. Preferably, said connection is a side-to-side anastomosis. Alternatively or additionally,

said connection is an end-to-side anastomosis. In a preferred embodiment of the invention, the method comprises connecting a second end of said graft to a second blood vessel, wherein said connection comprises an independent anastomosis.

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124694	מספר: Number
29-05-1998	תאריך: Date
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בקשה לפטנט
Application for Patent

088/00536

אני, (שם המבקש, מענו – ולגבי גוף מאוגד – מקום התאגדותו)
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METHODS AND DEVICES FOR VASCULAR SURGERY

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hereby apply for a patent to be granted to me in respect thereof.

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METHODS AND DEVICES FOR VASCULAR SURGERY

Dr. Ari Derowe Ltd.
c:088/00536

דר. ארי דירוא בע״מ

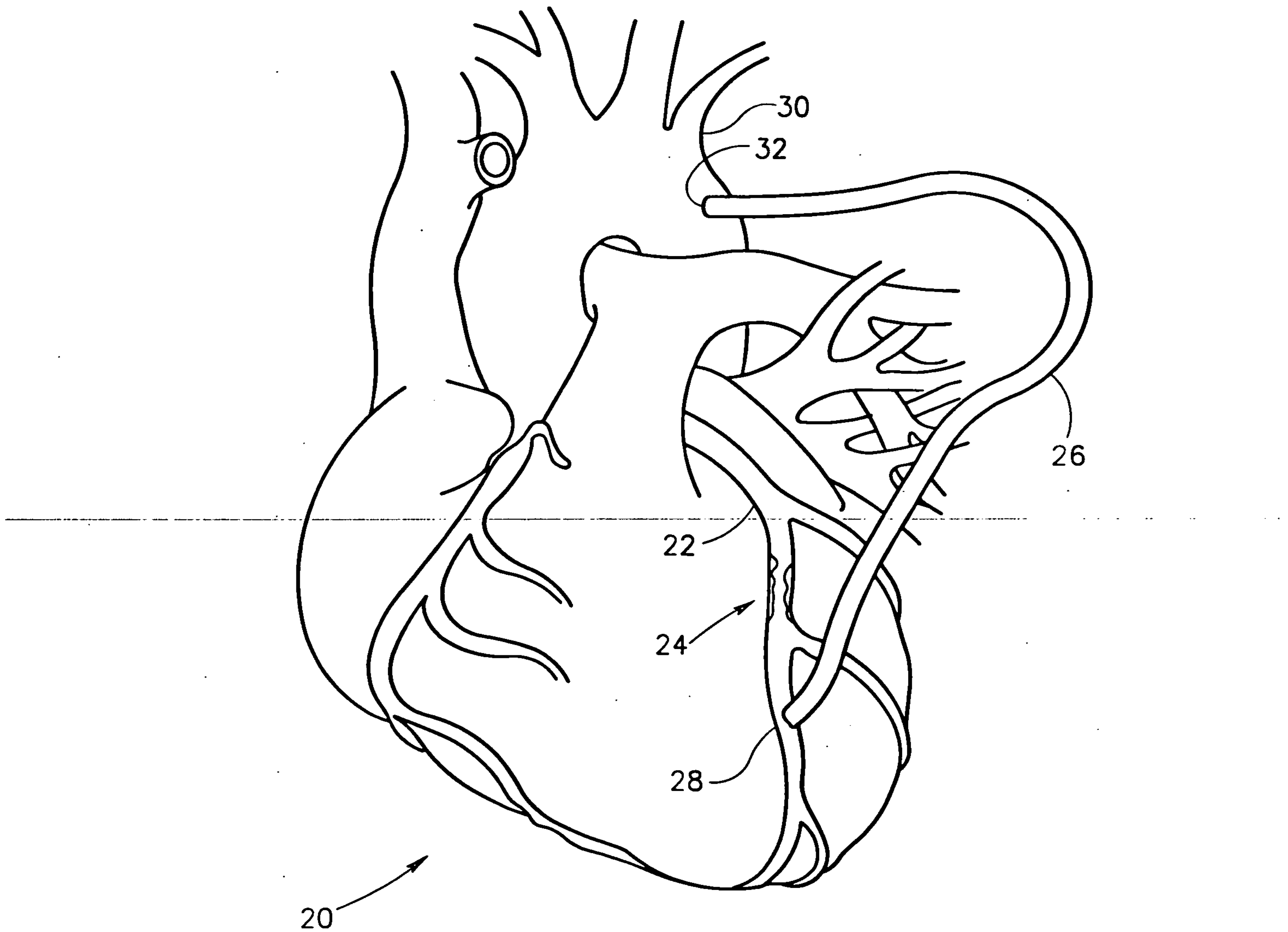


FIG. 1

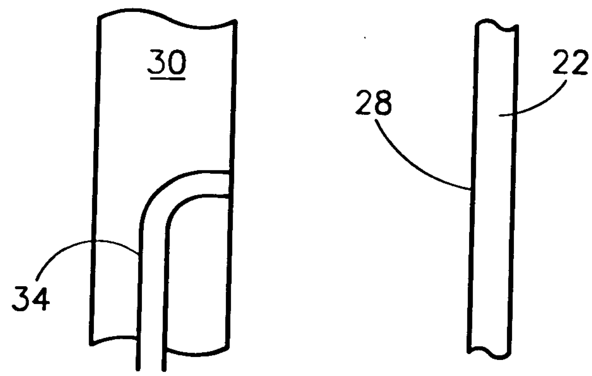


FIG.2A

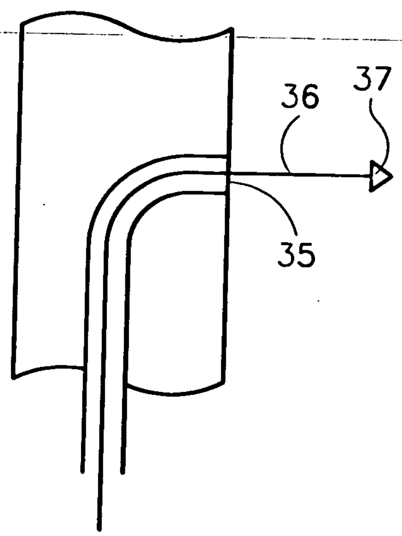


FIG.2B

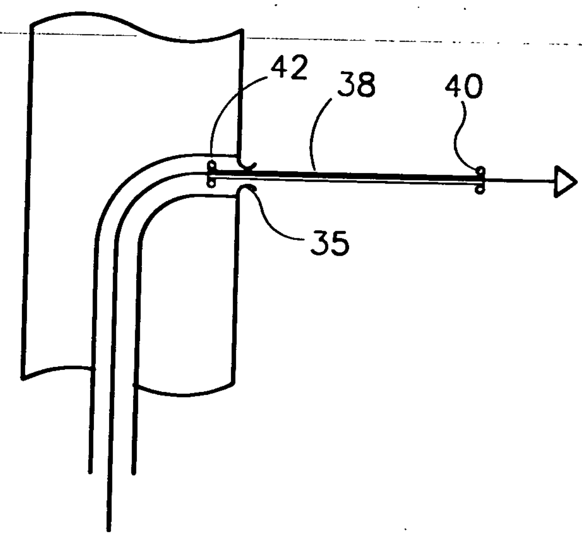


FIG.2C

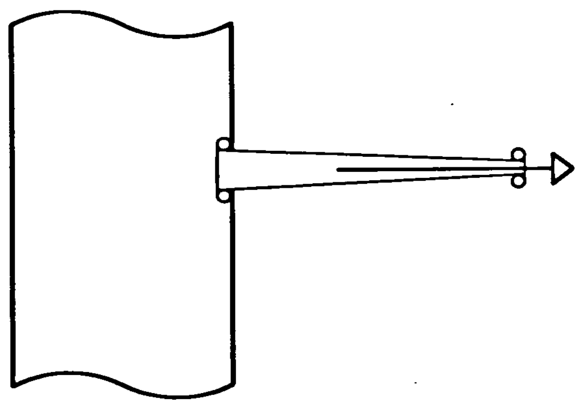


FIG.2D

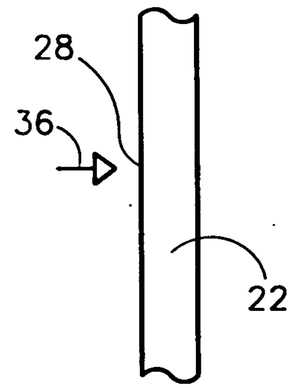


FIG.2E

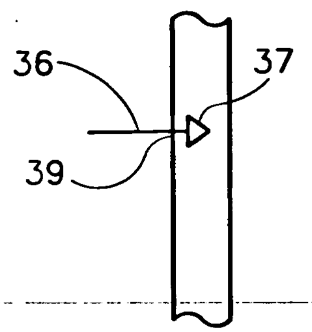


FIG.2F

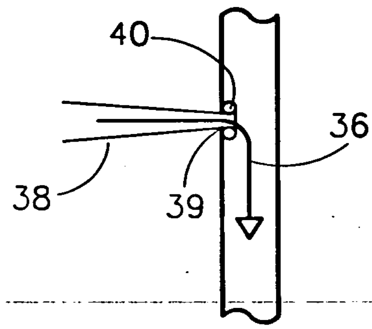


FIG.2G

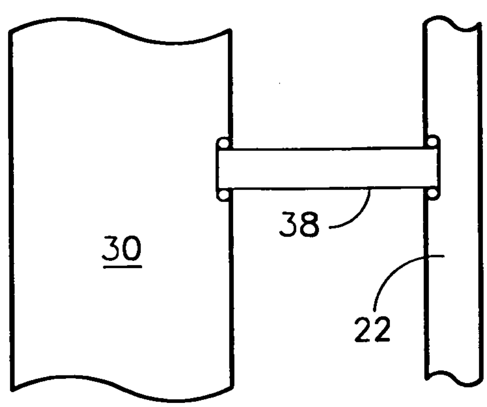


FIG.2H

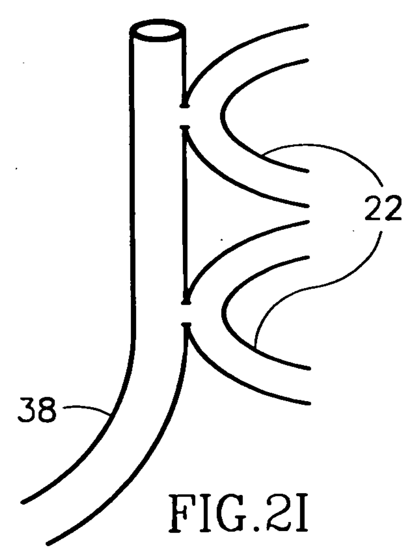


FIG.2I

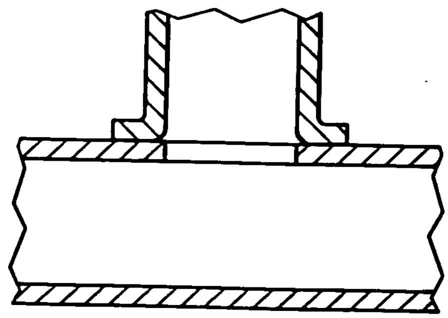


FIG.3A

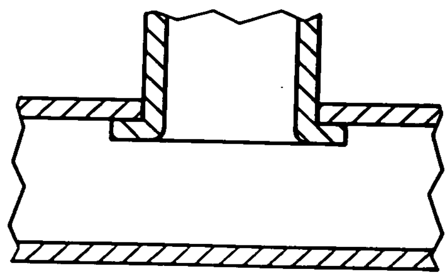


FIG.3B

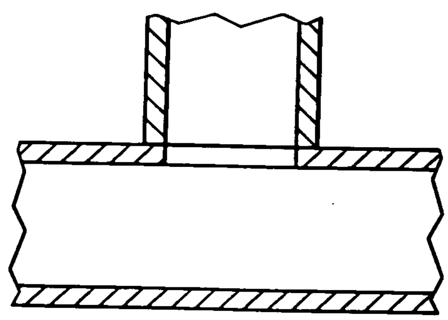


FIG.3C

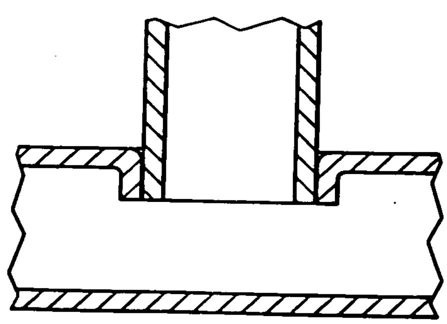


FIG.3D

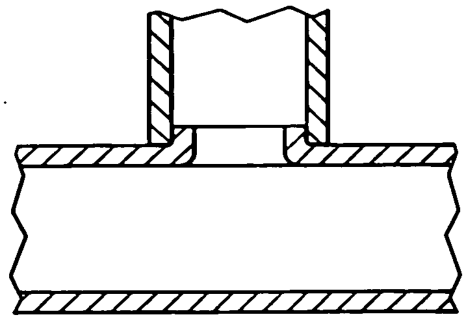


FIG.3E

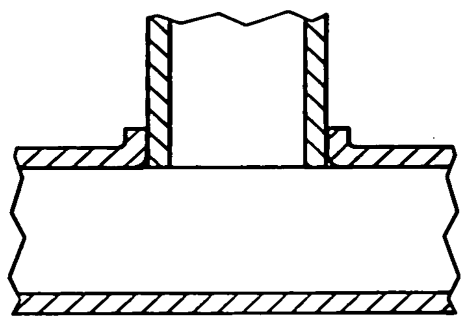


FIG.3F

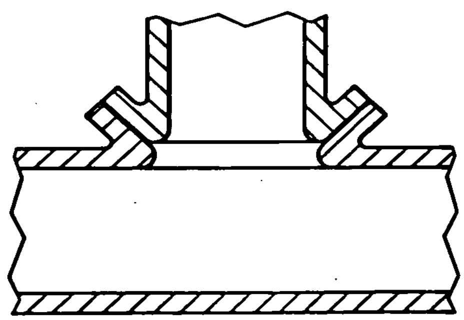


FIG.3G

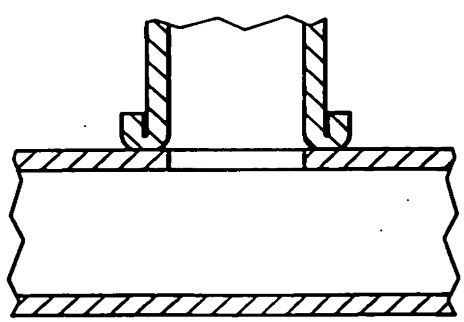


FIG.3H

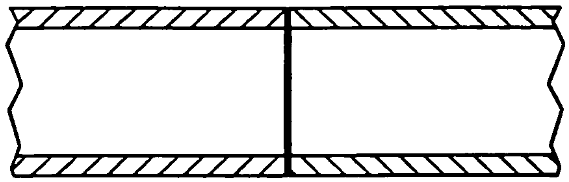


FIG.3I

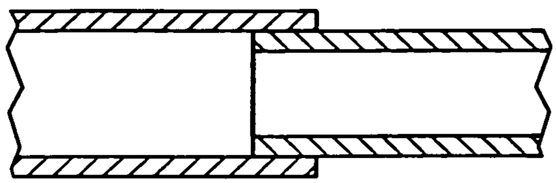


FIG.3J

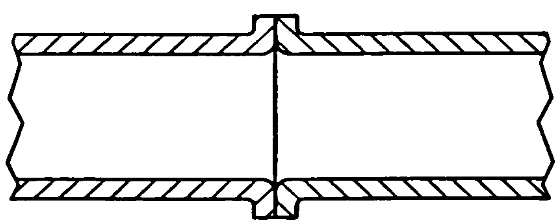


FIG.3K

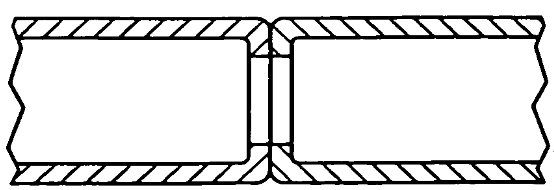


FIG.3L

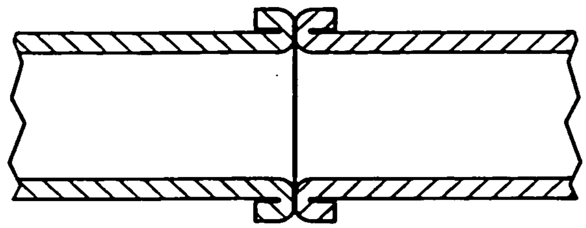


FIG.3M

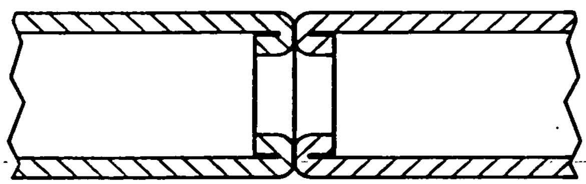


FIG.3N

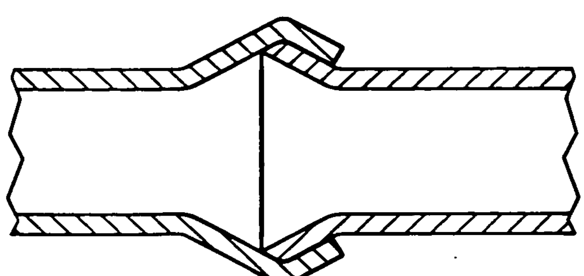


FIG.3O

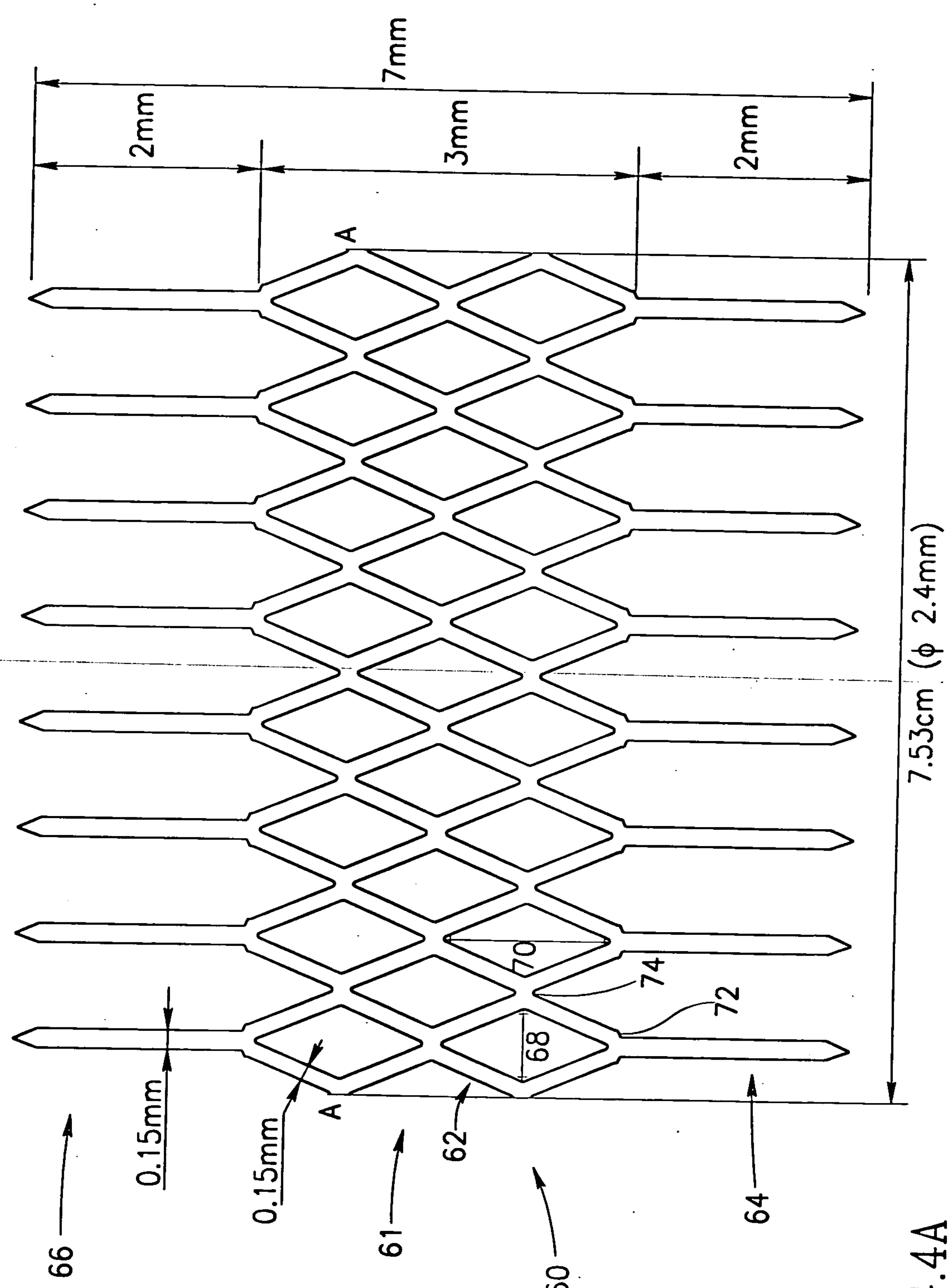

7mm
2mm
3mm
2mm
A
A
7.53cm (ϕ 2.4mm)
0.15mm
0.15mm
66
61
62
60
64
68
70
72
74

FIG.4A

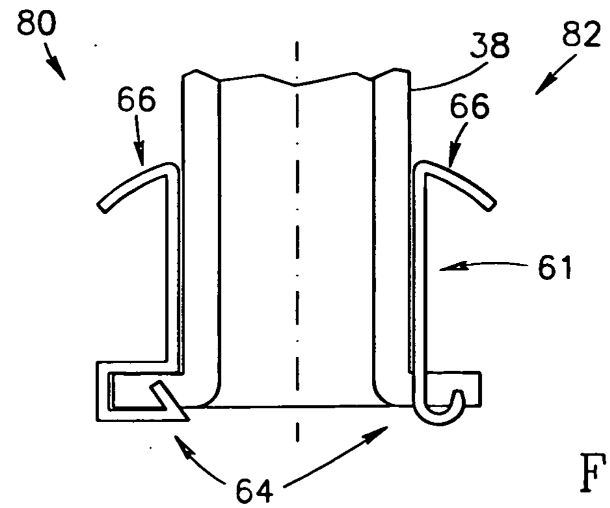


FIG.4B

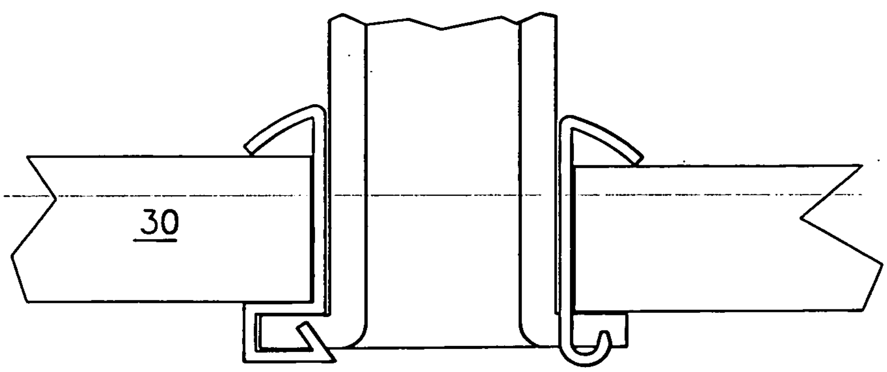


FIG.4C

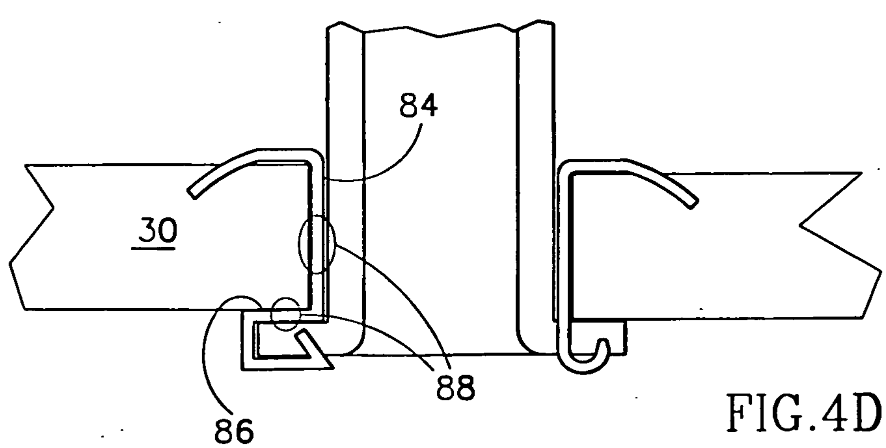


FIG.4D

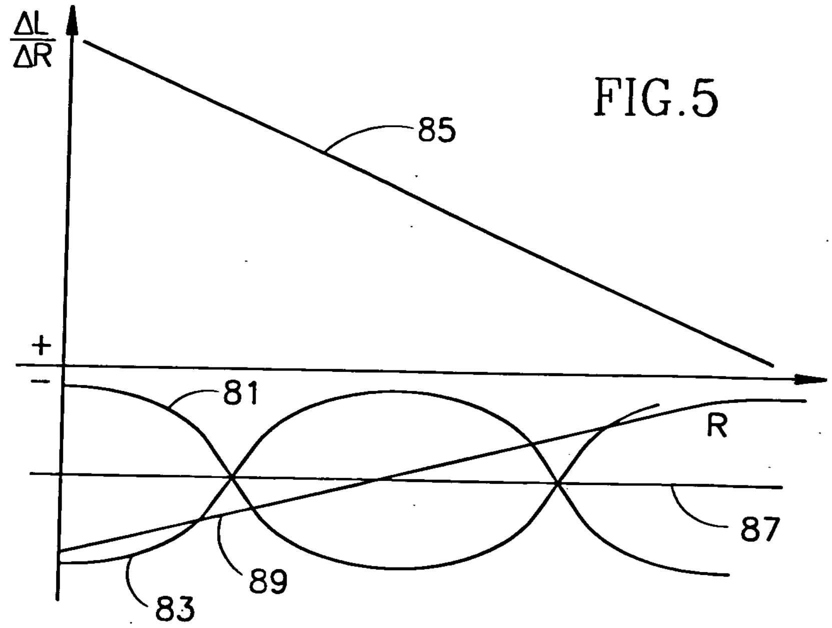


FIG.5

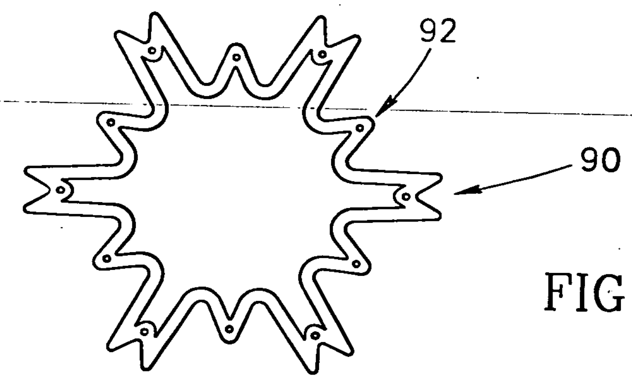


FIG.6A

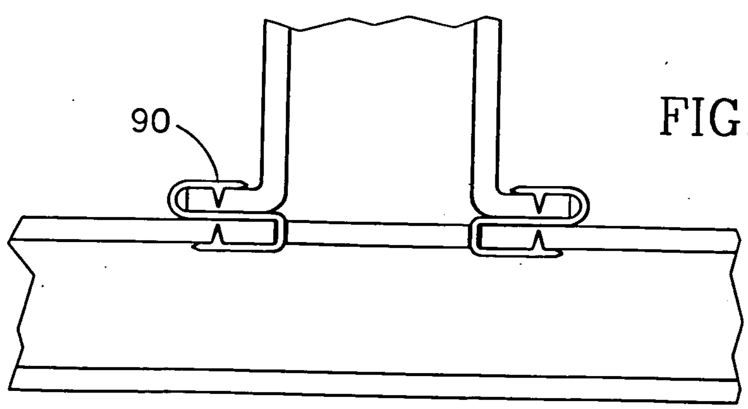


FIG.6B

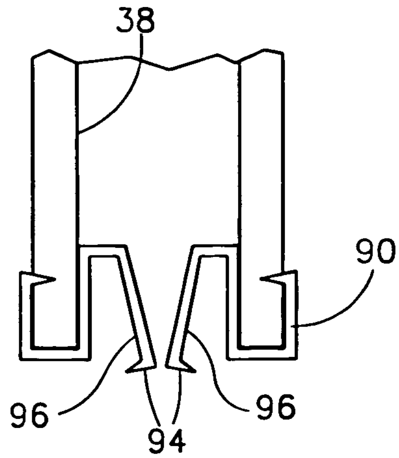


FIG.6C

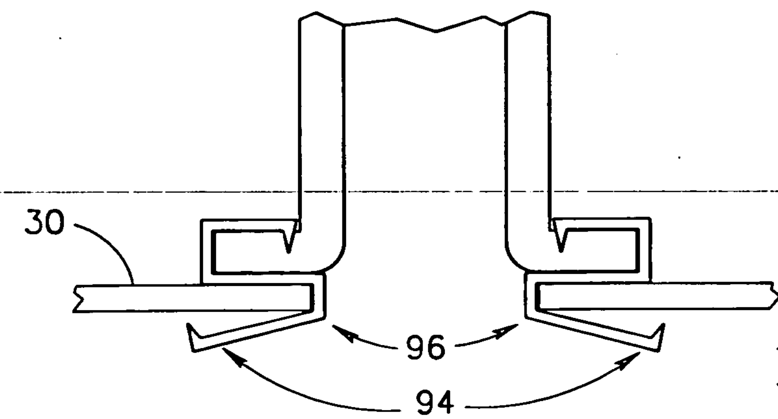


FIG.6D

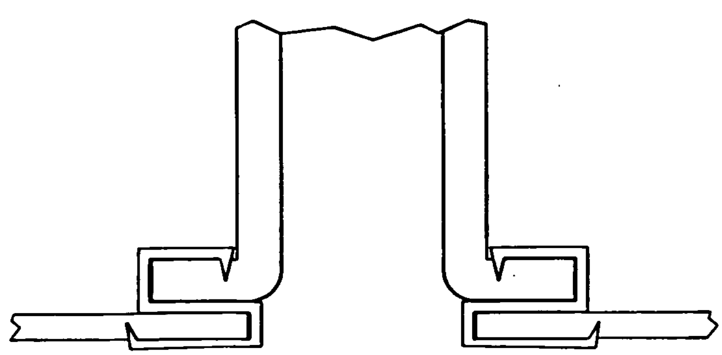


FIG.6E

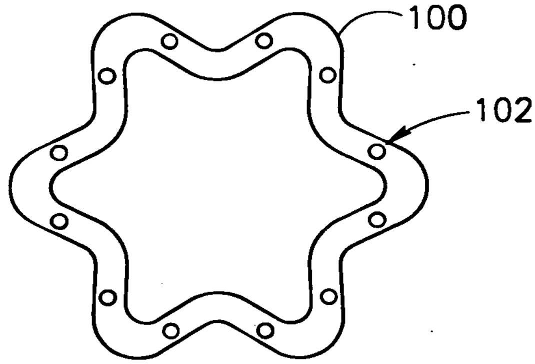


FIG.7A

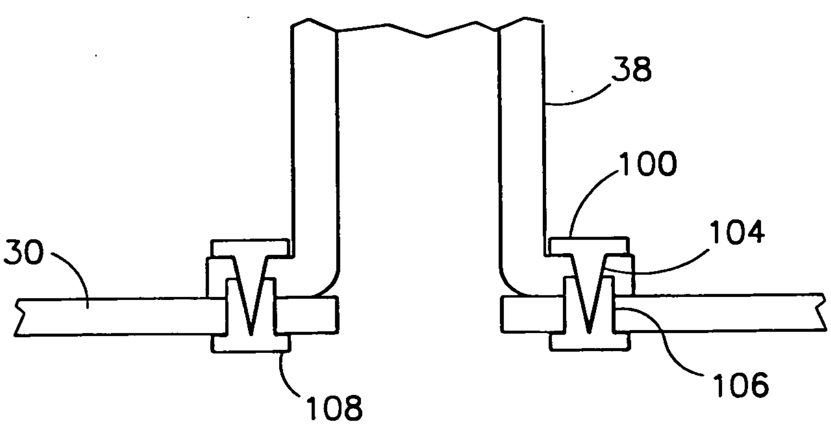


FIG.7B

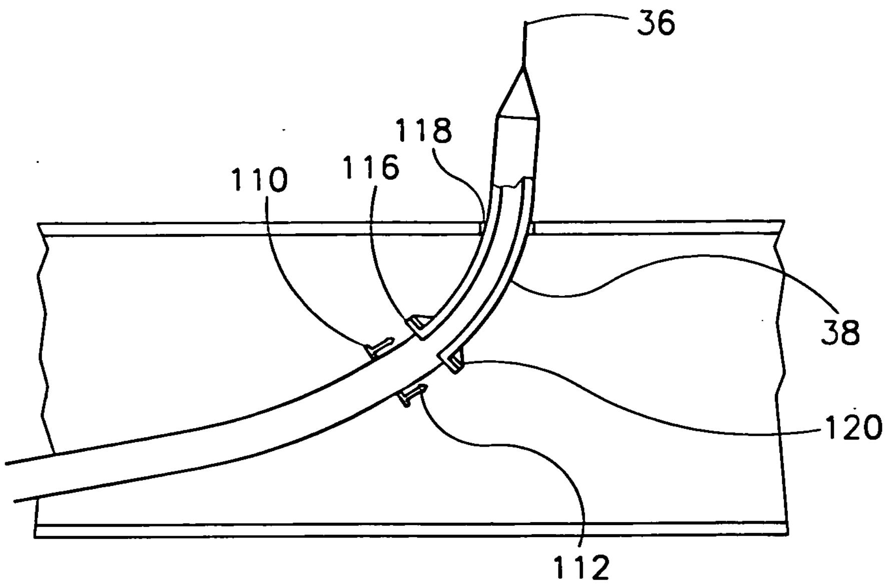


FIG.8A

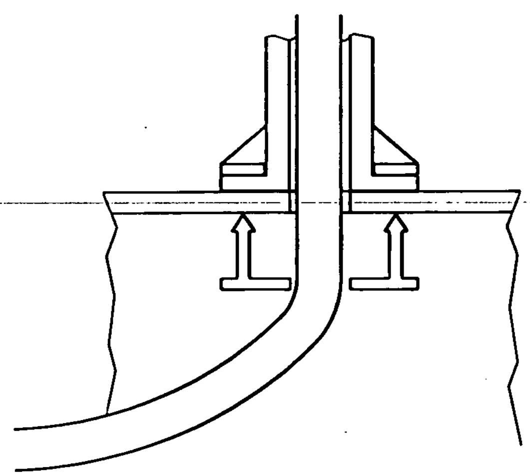


FIG.8B

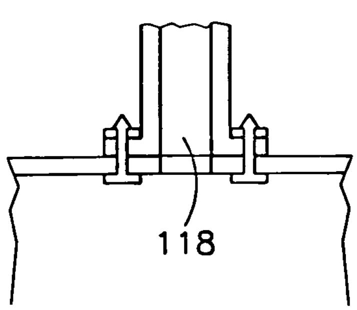


FIG.8C

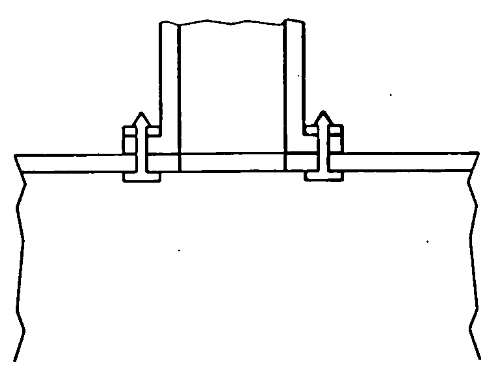


FIG.8D

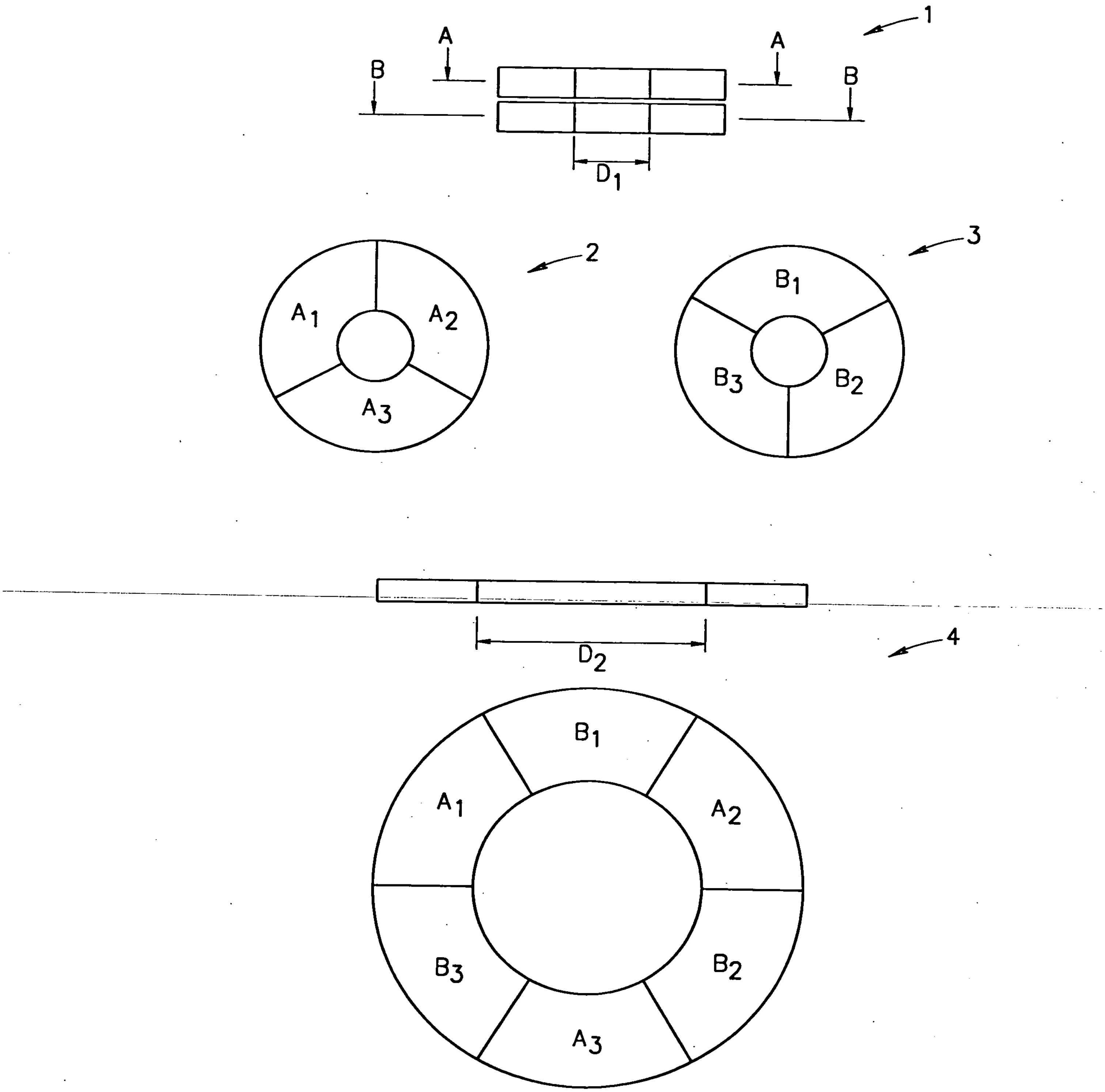


FIG.8E

FIG.8F

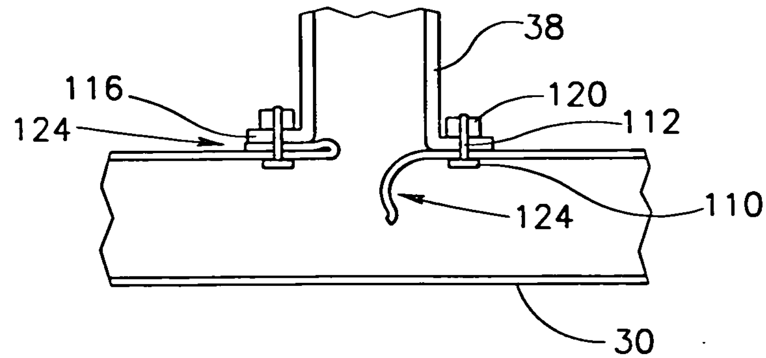


FIG.8G

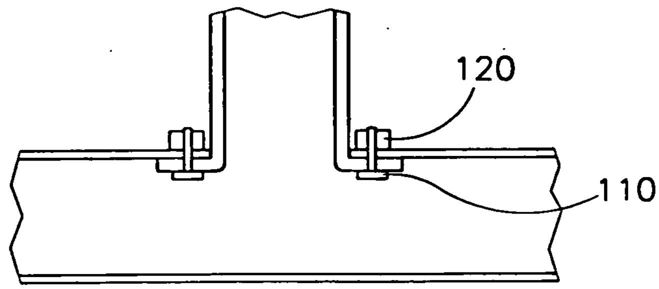


FIG.8H

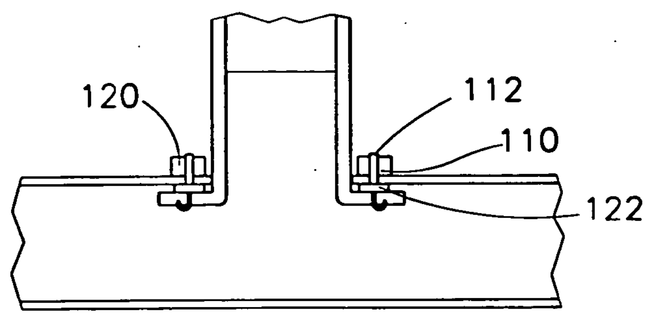
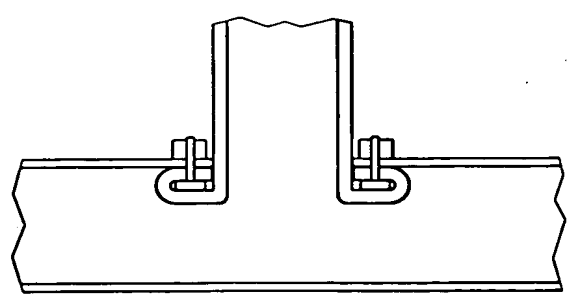


FIG.8I



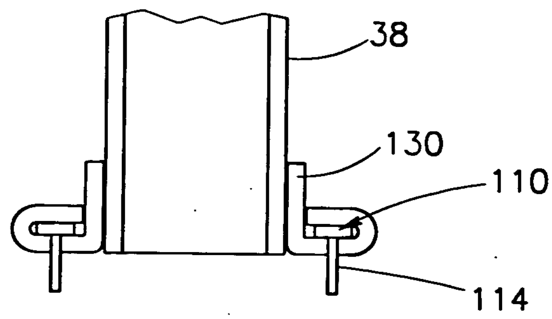


FIG.9A

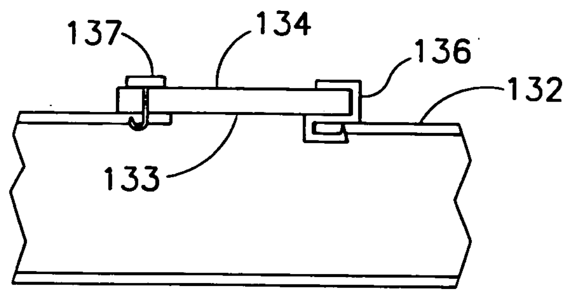


FIG.9B

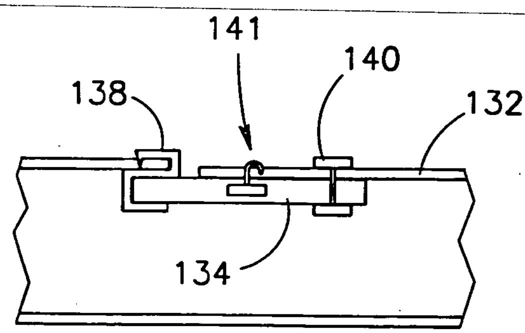


FIG.9C

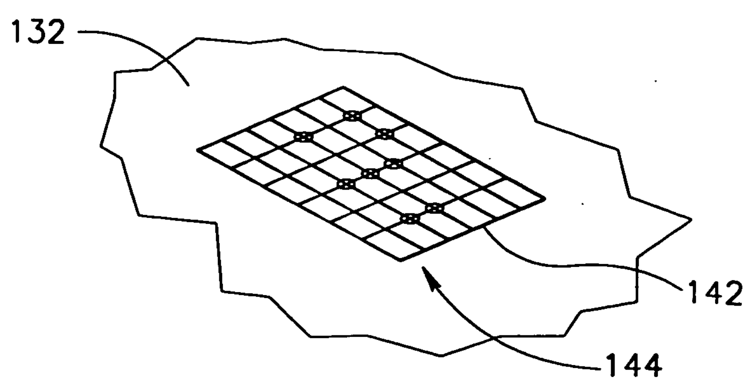


FIG.9D

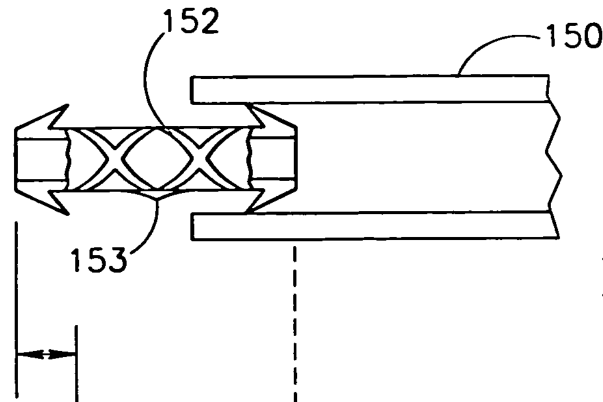


FIG.10A

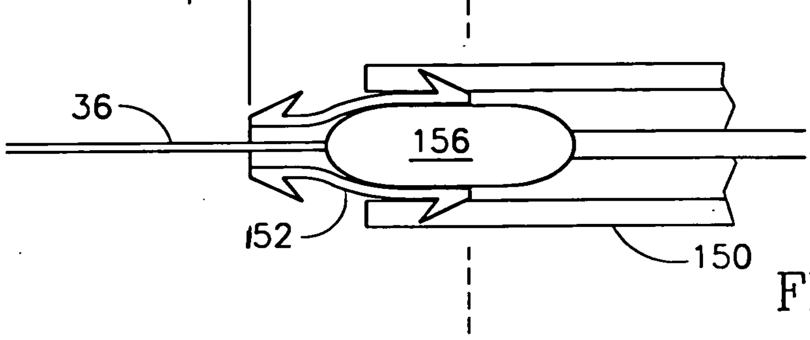


FIG.10B

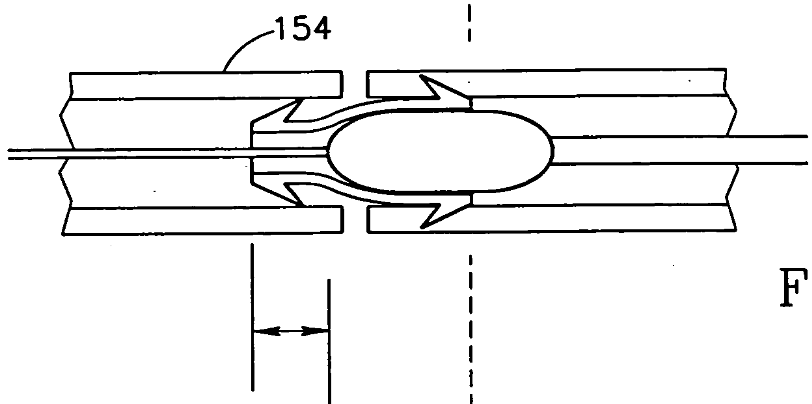


FIG.10C

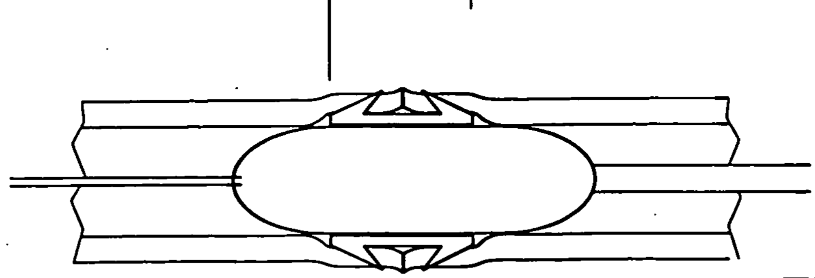


FIG.10D

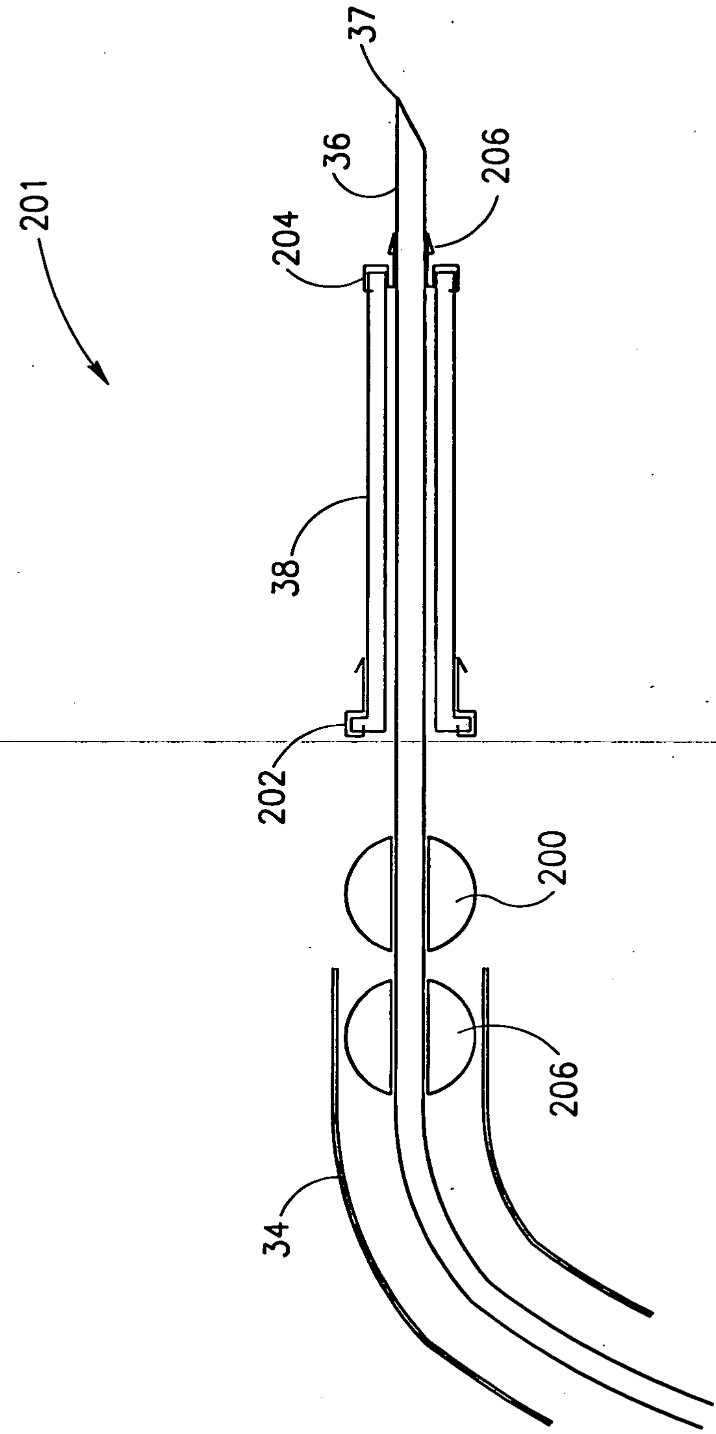


FIG.11